DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE MUNCHTUKATE, DEATROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE- dextroamphetamine sacharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate capsule, extended release Zydus Pharmaceuticals (USA) Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE SAPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE and AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES safely and effectively. See full prescribing information for DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE WELEASE CAPSULES.

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE and AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES, for oral use, CII

#### Initial U.S. Approval: 2001

WARNING: ABUSE AND DEPENDENCE WARING: ABUSE AND DEPENDENCE See full prescribing information for compilee boxed warning CNS stimulants, including DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE SAPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE and AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. (5.1, (9.3) Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. (9.2, (9.3)

- RECENT MAJOR CHANGES 7/2019 7/2019 7/2019

Boxed Warnings Dosage and Administration (2.1) Warnings and Precautions (5.1)

V&mings and Precautions (5.1) 7/2019 Textmampletamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suifate and amphetamine suifate extended-refaces capsules, a CKS stimulant, are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) (1) C Indiren (ages 6-12): Efficacy was established in one 3-week outpatient, controlled trial and one C Children (ages 6-12): Efficacy was established in one 4-week controlled trial and one AdDiscusses provide size as established in one 4-week controlled trial in adolescents with ADHD (14)

- ADHD. (14)
   Adults: Efficacy was established in one 4-week controlled trial in adults with ADHD. (14)
- Pediatric patient sloges 6-17 Ji 20 Moving Unit in maximum dose for children 6-12 years of gate 5 along once daily (22, 23, 2, 4) in the morning, Maximum dose for children 6-12 years of gate 5 along once daily (22, 23, 2, 4) in the morning data maximum dose for children 6-12 Adults: 20 mg once daily in the morning, (25) Pediatric patient sloges 6-17 Ji Win severe renal impairment: 5 mg once daily in the morning. Maximum dose for children 6-12 years of age with severe renal impairment is 20 mg once daily (2,6, 8,6)

- Adults with severe renal impairment: 15 mg once daily in the morning. (2.6, 8.6)
   Patients with ESRD: Not recommended. (2.6, 8.6)

## DOSAGE FORMS AND STRENGTHS Extended release Capsules: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg (3)

- CONTRAINDICATIONS

- CONTRAINDICATIO Advanced arteriosclerosis (4) Symptomatic cardiovascular disease (4) Moderate to severe hypertension (4) Hyperthyroidism (4) Known hypersensitivity or idiosyncrasy to amphetamine (4) Glaucoma (4)
- Agitated states (4)
- History of drug abuse (4) During or within 14 days following the administration of monoamine oxidase inhibitors (MAOI) (4, 7.1)
- usacury or using addises [4]
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- Tics: May exacerbate tics. Evaluate for tics and Tourette's syndrome prior to stimulant administration. (5.9)

- ADVERSE REACTIONS Children (ages 6 to 12): Most common adverse reactions (≥5% and with a higher incidence than on placebo) were loss of appetite, insomnia, abdominal pain, emutotial bality, vomition, nervousness, nausea, and fever. (6.1) Adolescents (loges 13 to 17): Most common adverse reactions (≥5% and with a higher incidence than on placebo) were loss of appetite, insomnia, abdominal pain, weight loss, and nervousness, (6.1) Adults: Most common adverse reactions z5% and with a higher incidence than on placebo were dry mouth, loss of appetite, insomnia, headache, weight loss, nausea, anxiety, agtation, dizziness, tachycardia, daminea, asthenda, and urinary tract infections. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Zydus at 1-877-993-8779 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

- versport SUSPECTED ADVERSE REACTONS, contact Zydus at 1-877-993-8779 or FDA at 1-800+FDA-1088 or waw(fda godmedwatch
   MAQI antidegressants are contraindicated; MAQIs potentiate the effects of amphetamine. Do not administer dextroamphetamine sacharate, amphetamine asparate monohydrate, dextroamphetamine sufface and amphetamine sufface and amphetamine. The second sec

## USE IN SPECIFIC POPULATIONS Pregnancy: May cause fetal harm. (8.1) Lactation: Breastfeeding not recommended. (8.2)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 7/2019

### FULL PRESCRIBING INFORMATION: CONTENTS\* WARNING ABUSE AND DEPENDENCE 1 INDICATIONS AND USAGE

- 1.1 Attention Deficit Hyperactivity Disorder 2 DOSAGE AND ADMINISTRATION
- 2.1 Important Information Prior to Initiating Treatment 2.2 Dosing Considerations for all Patients 2.3 Children 2.4 Adolescents

- 2.4 Adolescents 2.5 Adults 2.6 Dosane in Pr

- 2.5 Adults 2.6 Dosage in Patients with Renal Impairment 3 DOSAGE FORMS AND STRENGTHS 4 CONTRAINDICATIONS 5 WARNINGS AND PRECAUTIONS 5.1 Potential for Abuse and Dependence 5.2 Serious Cardiovascular Reactions 5.3 Psychiatric Adverse Events 5.4 Long-Term Suppression of Growth 5.5 eParinberal Vasculonathy. Including Paynal 5.5 SetZures 5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon 5.7 Serotonin Syndrome 5.8 Visual Disturbance

- 5.9 Tics
- 5.10 Prescribing and Dispensing 6 ADVERSE REACTIONS
- 6.1 Clinical Studies Experience 6.2 Adverse Reactions Associated with the Use of Amphetamine,
- 0.2 Autors of reactions Associated with the Ose of Anniphetamine, Dextroamphetamine Suffate and Amphetamine Aspartate Monohydrate, Dextroamphetamine Suffate and Amphetamine Aspartate Monohydrate, or Dextroamphetamine Suffate and Amphetamine Aspartate Monohydrate, Dextroamphetamine Suffate and Amphetamine Suffate Tablets 7 DRUG INTERACTIONS

7.1 Clinically Important Interactions with Amphetamines 8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy 8.2 Lactation 8.4 Pediatric Use 8.5 Geriatric Use 8.6 Renal Impairment 9 DRUG ABUSE AND DEPENDENCE Controlled Substance Abuse 9.3 Dependence 10 OVERDOSAGE 10 OVERDOSAGE 11 DESCRIPTION 12 CLINICAL PHARMACOLOGY 12.1 Mechanism of Action 12.2 Pharmacodynamics 12.3 Pharmacokinetics 13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility 13.2 Animal Toxicology and/or Pharmacology 14 CLINICAL STUDIES 15 HOW CUBPLEP/CTOREGE AND HANDLING 14 CLINICAL STODIES 16 HOW SUPPLIED/STORAGE AND HANDLING 17 PATIENT COUNSELING INFORMATION \* Sections or subsections omitted from the full prescribing information are not listed.

#### FULL PRESCRIBING INFORMATION

WARNING ABUSE AND DEPENDENCE

CNS stimulants, including DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE and AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES, SolFAI E allo AMPIFIC IMPIRE SOLFAI E EXTENDED-RELEASE CHASOLES, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy [see Warnings and Precautions (5.1) and Drug Abuse and Dependence (9.2, (9.3)].

#### 1 INDICATIONS AND USAGE

#### 1.1 Attention Deficit Hyperactivity Disorder

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are indicated for the treatment of attention deficit hyperactivity disorder (ADHD).

The efficacy of dextroamphetamine sachards, amphetamine aspartate monhydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in the treatment of ADHD was established on the basis of two controlled trials in children age 6 to 12, one controlled trial in adolescents aged 13 to 17, and one controlled trial in adults who met DSM-IV® criteria for ADHD [see Clinical Studies (14)]. aged

adults who met DSM-IV® criteria for ADHD [see Clinical Studies (14)]. A diagnosis of ADHD (DSM-IV®) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the inattentive Type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to detalis/carless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; bases thing; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: lidgeting/squirming; leaving seat; inappropriate running/clinibing; ifficulty with quiet activities; "on the go;" excessive taking; buirting answers; can wait turn; intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

#### Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the patient and not solely on the presence of the required number of DSM-IV® characteristics.

#### Need for Comprehensive Treatment Program

Need for Comprehensive Treatment Program Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological educational, social) for patients with this syndrome. Drug treatment may not be indicated for all patients with this syndrome. Stimulants are not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

#### Long-Term Use

The effectiveness of dextroamphetamine saccharate, amphetamine aspartate Ine effectiveness of extroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate extended-release capsules for long-dextroamphetamine sulfate extended-release capsules for long-dextroamphetamine sulfate extended-release adolescents and adults, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use dextroamphetamine suffate and amphetamine amphetamine supartate monohydrate, dextroamphetamine suffate and amphetamine amphetamine suffate and amphetamine suffate and amphetamine for the superstant and the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and amphetamine for the suffate and for the suffate and for the suffate and for the suffate and amphetamine for the suffate and for the suffate and the suff sulfate extended-release capsules for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

#### 2 DOSAGE AND ADMINISTRATION

#### 2.1 Important Information Prior to Initiating Treatment

Prior to initiating treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, assess for the presence of cardiac disease (e.g., perform a cardul history, family history of sudden death or ventricular arrhythmia, and physical exam [see Warning and Precautions (5.2)].

Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy. Mantain careful prescription records, educate patients about abuse, monitor for signs for abuse and overdose, and periodically re-evaluate the need for dextroamphetamine saccharate, amphetamine supartate monohydrate, dextroamphetamine suface and amphetamine sufate extended-release capsules use [see Warning and Precautions (5.1), Drug Abuse and Dependence (9)].

#### 2.2 Dosing Considerations for all Patients

Individualize the dosage according to the therapeutic needs and response of the patient. Administer dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate actended-release capsules at the lowest effective dosage.

Based on bioequivalence data, patients taking divided doses of immediate-release Based on biolequivalence data, patients taking divided doses of mmediate-release dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate tablets (for example, twice daily), may be switched to dextroamphetamine soucharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules at the same total daily dose taken once daily. Titrate at weekly intervals to appropriate efficacy and tolerability as indicated.

appropriate efficacy and tolerability as indicated. Dextroamphetamine saccharate, amphetamine asparate monohydrate, dextroamphetamine suifate and amphetamine suifate extended-release capsules may be taken whole, or the capsule may be opened and the entire contents sprinkled on applesauce. If the patient is using the sprinkle administration method, the sprinkled applesauce should be consumed immediately; it should not be stored. Patients should take the applesauce with sprinkled beads in its entirety without chewing. The dose of a single capsule should not be divided. The contents of the entire capsule should be taken, and patients should not take anything less than one capsule per day.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may be

#### taken with or without food.

dextroampletamine saccharate, amphetamine aspartate monohydrate, dextroampletamine sulfate and amphetamine sulfate extended-release capsules should be given upon awakening. Afternoon doses should be avoided because of the potential for insomia.

Where possible, dextroamphetamine saccharate, amphetamine aspartate monohydrate. White possible, tech using the and ampletamine section and the sparate possible of the sparate possibl

#### 2.3 Children

2.3 Children
In children with ADHD who are 6-12 years of age and are either starting treatment for the first time or switching from another medication, start with 10 mg once daily in the morning; daily dosage may be adjusted in increments of 5 mg or 10 mg at weekly intervals. When in the judgment of the clinician a lower initial dose is appropriate, patients may begin treatment with 5 mg once daily in the morning. The maximum recommended dose for children 6-12 years of age is 30 mg/day; doses greater than 30 mg/day of have not been studied in children. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine sulfate extended-release capsules has not been studied in children under 6 years of age.

#### 2.4 Adolescents

The recommended starting dose for adolescents with ADHD who are 13-17 years of age and are either starting treatment for the first time or switching from another medication is 10 mg/day. The dose may be increased to 20 mg/day after one week if ADHD symptoms are not adequately controlled.

#### 2.5 Adults

In adults with ADHD who are either starting treatment for the first time or switching from another medication, the recommended dose is 20 mg/day.

#### 2.6 Dosage in Patients with Renal Impairment

In adult patients with severe renal impairment (GFR 15 to < 30 mL/min/1.73m<sup>2</sup>), the recommended dose is 15 mg once daily in the morning. In pediatric patients (6 to 17 years of age) with severe renal impairment, the recommended dose is 5 mg once daily. The maximum dose for children 6 to 12 years of age with severe renal impairment is 20 mg once daily. Dextroamphetamine sacharate, amphetamine sacharate monohydrate, dextroamphetamine sulfate and amphetamine sacharate, as the (SER) (GFR < 15 mL/min/1.73m<sup>2</sup>) [see Use In Specific Populations (8.6), Clinical Pharmacology (12.3)].

#### 3 DOSAGE FORMS AND STRENGTHS

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are available as:

5 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1184' in black ink and light orange opaque body imprinted 'N' in black ink.

10 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1185' in black ink and light blue opaque body imprinted 'N' in black ink.

15 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1186' in black ink and white opaque body imprinted 'N' in black ink.

20 mg: Hard gelatin capsules with light orange opaque cap, imprinted '1187' in black ink and light orange opaque body imprinted 'N' in black ink.

25 mg: Hard gelatin capsules with light orange opaque cap, imprinted '1188' in black ink and white opaque body imprinted 'N' in black ink.

30 mg: Hard gelatin capsules with white opaque cap, imprinted '1189' in black ink and white opaque body imprinted 'N' in black ink.

#### 4 CONTRAINDICATIONS

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules administration is contraindicated in patients with the following conditions: • Advanced arterioscieross

- Symptomatic cardiovascular disease Moderate to severe hypertension
- Hyperthyroidism
- Inpatients known to be hypersensitive to amphetamine, or other components of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products [see Adverse Reactions (6.2)]
- Glaucoma Agitated states
- History of drug abuse

Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of an increased risk of hypertensive crisis [see Warnings and Precautions (5.6) and Drug Interactions (7.1)]

#### **5 WARNINGS AND PRECAUTIONS**

#### 5.1 Potential for Abuse and Dependence

CNS stimulants, including DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES, other amphetamine-containing products, an methylphenidate, have a high potential for abuse and dependence while on therapy [see Boxed Warning, Drug Abuse and Dependence (9.2, 9.3)].

#### 5.2 Serious Cardiovascular Reactions

Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems

#### Children and Adolescents

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardionyopathy, addressense with Klowin seriods solution can dia can dia with an end of the seriods and the seriod s

#### Adults

Studien deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelinood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs [see Contraindications (4)].

#### Hypertension and Other Cardiovascular Conditions

Hypertension and Unter Lardiovascular Londtons Stimulant medications cause a modes increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia [see Contraindications (4) and Adverse Reactions (6)].

Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

#### 5.3 Psychiatric Adverse Events

#### Pre-Existing Psychosis

Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with pre-existing psychotic disorder.

#### Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD patients with comorbid biolar disorder because of concern for possible induction of mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients with the comorbid depressive symptoms should be adequately screened to determine if they are at risk for biolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, biolar disorder, and depression.

#### Emergence of New Psychotic or Manic Symptoms

Treatment-emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3.482 exposed to methyphenidate or ampletamine for several week at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients. eks Aggression

# Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the postmarketing experience of son medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.

#### 5.4 Long-Term Suppression of Growth

Monitor growth in children during treatment with stimulants. Patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

growing or gaining weight as expected may need to have their treatment interrupted. Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth n height and 2.7 Kg less growth in weight over 3 years), without evidence of growth rebound during this period of development.

In a controlled trial of dextroamphetamine saccharate, amphetamine aspartate In a controlled transfer of exclosing the section and any amplitude management of the sector and dextroamplexamme subtriarder, ampletamme apparate innormydrate, dextroamplexamme suffate and ampletamme suffate extended-release capsules. Higher doses were associated with greater weight boss within the initial 4 weeks of treatment. Chronic use of ampletammes can be expected to cause a similar suppression of arowth

#### 5.5 Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in the absence of seizures, and very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamene sulfate extended-release capsules should be discontinued.

#### 5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon

5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon Stimulants, including dextroamphetamine sucharate, amphetamine aspartate monohydrate, dextroamphetamine sullate and amphetamine sullate extended-release capsules, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ukeration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants, Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

#### 5.7 Serotonin Syndrome

5.7 Serotonin Syndrome Serotonin syndrome, a potentially life-threatening reaction, may occur when amphetamines are used in combination with other drugs that affect the serotonergic neurotransmitter systems such as MAOIs, selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (MSNIs), triptans, tricyclic antidepressants, fentanyl, Rhium, tramadol, tryptophan, buspirone, and St. John's Wort (See Drug Interactions (7.1)). Amphetamines and amphetamine derivatives are known to be metabolized, to some degree, by cytochrome P450 2D6 (CYP2D6) and display minor inhibition of CYP2D6 metabolism [see Clinical Pharmacology (12.3)]. The potential for a pharmacokinetic interaction exists with the co-administration of CYP2D6 inhibitors which may increase the risk with increased exposure to dextroamphetamine sacharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine suffate extined-release capsules. In these situations, consider an afternative non-serotonergic drug or an alternative drug that does not inhibit CYP2D6 [see Drug Interactions (7.1)]. Serotonin syndrome symptoms may include mental status changes (e.g., agitation, halucinations, delirum, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., temor, rigidity, mycclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). diarrhea).

Concomitant use of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with MAOI drugs is contraindicated [see Contraindications (4)].

Discontinue treatment with dextroamphetamine saccharate, amphetamine aspartate Decomparise of extension and decompletion in the sector and processing of the operation of the sector and processing of the sector and the se serotonn syndrome occur, and intake supportive symptomatic treatment. Concomiant use of dextroamphetamine saccharate, amphetamine asparate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with other serotonergic drugs or CrtP206 initibors should be used only if the potential benefit justifies the potential risk. If clinically warranted, consider initiating dextroamphetamine saccharate, amphetamine asparate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with lower doses, monitoring patients for the emergence of serotonin syndrome during drug initiation or titration, and informing patients of the increased risk for serotonin syndrome.

#### 5.8 Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

#### 5.9 Tics

Amphetamines have been reported to exacerbate motor and phonic tics and Tourette's syndrome. Therefore, clinical evaluation for tics and Tourette's syndrome in patients and their families should precede use of stimulant medications.

#### 5.10 Prescribing and Dispensing

The least amount of amphetamine feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules should be used with caution in patients who use other sympathomimetic drugs

### 6 ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The premarketing development program for dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules included exposures in a total of 1,315 participants in clinical trials (635 pediatric patients, 350 adolescent patients, 248 adult patients, and 82 healthy adult subjects). Of these, 635 patients (ages 6 to 12) were evaluated in two controlled clinical struide, one open-label clinical struid, and two single-dose clinical pharmacobgy studies (N= 40). Safety data on all patients are included in the discussion that follow. Adverse raretines were assessed by collecting adverse tractions, resulted that follows. Adverse reactions were assessed by collecting adverse reactions, results of physical examinations, vital signs, weights, laboratory analyses, and ECGs.

Adverse reactions during exposure were obtained primarily by general inquiry and Adverse reactions during exposure were obtained primarly by general induiry and recorded by clinical investigators using terminology of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse reactions without first grouping similar types of reactions into a smaller number of standardized event categories. In the tables and listings that follow, COSTART terminology has been used to classify reported adverse reactions.

The stated frequencies of adverse reactions represent the proportion of individua experienced, at least once, a treatment-emergent adverse event of the type listed Adverse Reactions Leading to Discontinuation of Treatment

In two piacebo-controlled studies of up to 5 weeks duration among children with ADHD, 2.4% (10)425) of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules-treated patients discontinued due to advese reactions (including 3 patients with loss of appetite, one of whom also reported insomnia) compared to 2.7% (7/259) receiving placebo.

The most frequent adverse reactions leading to discontinuation of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in controlled and uncontrolled, multiple-dose clinical trials of children (N=59s) were anorexia (loss of appetite) (2.9%), insomnia (1.5%), weight loss (1.2%), emotional lability (1%), and depression (0.7%). Over haif of these patients were exposed to dextroamphetamine sulfate and amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended refore capsules for 13 mention er meno extended-release capsules for 12 months or more.

In a separate placebo-controlled 4-week study in adolescents with ADHD, five patients In a separate pacebo-controlled 4-week study in adolescents with ADHU, twe patents (2.1%) discontinued treatment due to adverse events among dextroamphetamine saccharate, amphetamine asparate monohydrate, dextroamphetamine suffate and amphetamine suffate extended-release capsules treated patients (N=23) compared to none who received placebo (N=54). The most frequent adverse event leading to discontinuation and considered to be drug-related (i.e., leading to discontinuation in at least 1% of dextroamphetamine sucharate, amphetamine asparate monohydrate, dextroamphetamine suffate extended-release capsules-treated patients and at a rate at least twice that of placebo) was insomnia (1.3%, n=3).

patients and at a rate at least twice that of placebo) was insomnia (1.3%, n=3). In one placebo-controlled 4-week study among adults with ADHD with doses 20 mg to 60 mg, 23 patients (12.0%) discontinued treatment due to adverse events among dextroamphetamine saccharate, amphetamine sufface extended-release capsules-treated patients (N=191) compared to one patient (1.6%) who received placebo (N=64). The most frequent adverse events leading to discontinuation and considered to be drug-related (i.e., leading to discontinuation in at least 1% of dextroamphetamine sufface saccharate, amphetamine sufface sufface and amphetamine sufface studies and amphetamine sufface stended-release capsules-treated platents and at a rate at least twice that of placebo) were insomnia (5.2%, n=10), anxiety (2.1%, n=4), nervousness (1.6%, n=3), dry mouth (1.6%, n=3), and sthenia (1.0%, n=2).

#### Adverse Reactions Occurring in Controlled Trials

Adverse reactions reported in a 3-week clinical trial of children and a 4-week clinical trial in adolescents and adults, respectively, treated with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules or placebo are presented in the tables below.

## Table 1: Adverse Reactions Reported by 2% or More of Children (6-12 Years Old) Receiving Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules with Higher Incidence Than on Placebo in a 584-Patient Clinical Study

Body System	Preferred Term	Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules (n=374)	Placebo (n=210)
General		5% 4%	10% 2% 2% 2% 0%
Digestive System	Loss of Appetite Vomiting Nausea Dyspepsia	7%	2% 4% 3% 1%
			2% 2% 2% 0%
Metabolic/Nutritiona	Weight Loss	4%	0%

## Table 2: Adverse Reactions Reported by 5% or More of Adolescents (13-17 Years Old) Weighing ≤ 75 kg/165 lbs Receiving Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules with Higher Incidence Than Placebo in a 287 Patient Clinical Forced Weekly-Dose Titration Study\*

Body System	Preferred Term	Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules (n=233	)Placebo (n=54)
General	Abdominal Pain (stomachache)	11%	2%
Digestive System	Loss of Appetite <sup>b</sup>	36%	2%
Nervous System	Insomnia <sup>b</sup>	12%	4%
Nervous System	Nervousness	6%	6% <sup>a</sup>
Metabolic/Nutritiona	Weight Loss <sup>b</sup>	9%	0%
*Included doses up to 40		•	
<sup>a</sup> Appears the same due to	rounding		

<sup>b</sup>Dose-related adverse reactions

Note: The following reactions did not meet the criterion for inclusion in Table 2 but were reported by 2% to 4% of adolescent patients receiving dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with a higher incidence than patients receiving placebo in this study: accidental injury, asthenia (fatigue), dry mouth, dyspepsia, emotional lability, nausea, somnolence, and vomiting.

## Table 3: Adverse Reactions Reported by 5% or More of Adults Receiving Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules with Higher Incidence Than on Placebo in a 255 Patient Clinical Forced Weekly-Dose Titration Study\*

Body System referred Term Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules (n=191)Placebo (n=64) General Asthenia Dry Mouth Loss of Appetite 9% 35% Digestive System 33% 3% Nausea Diarrhea Insomnia 27% 13% Agitation 8% Nervous System Anxiety 8% Dizzinéss ervousness 13% Cardiovascular System Tachycardia letab ic/Nutritional Weight Loss Urogenital System Urinary Tract Infection 5%

\*Included doses up to 60 mg

Appears the same due to rounding Note: The following reactions did not meet the criterion for inclusion in Table 3 but were reported by 2% to 4% of adult patients receiving dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with a higher incidence than patients receiving placebo in this study; infection, photosensitivity reaction, constipation, tooth disorder (e.g., teeth clenching, tooth infection), emotional lability, libido decreased, somnolence, speech disorder (e.g., stuttering, excessive speech), palpitation, twitching, dyspnea, sweating, dysmenorrhea, and impotence.

#### Hypertension [see Warnings and Precautions (5.3)]

<u>Hypercension</u> [see Warnings and Precautions (5.-3)] In a controlled 4-week outpatient clinical study of adolescents with ADHD, isolated systolic blood pressure elevations  $\geq$  15 mmHg were observed in 7/64 (11%) placebo-treated patients and 7/100 (7%) patients receiving dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 10 or 20 mg. Isolated elevations in diastolic blood pressure 28 mmHg were observed in 16/64 (25%) placebo-treated patients and 22/100 (22%) dextroamphetamine sucharate, amphetamine supartate monohydrate, dextroamphetamine sulfate and amphetamine suffate extended-release capsules-treated patients. Similar results were observed at higher doses.

In a single-dose pharmacokinetic study in 23 adolescents with ADHD, isolated increase: in systolic blood pressure (above the upper 95% CI for age, gender, and stature) were observed in 21/1 (12%) and 8/23 (35%), subjects administered 10 mg and 20 mg

dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, respectively. Higher single doses were associated with a greater increase in systolic blood pressure. All increases were transient, appeared maximal at 2 to 4 hours post dose and not associated with symptoms.

6.2 Adverse Reactions Associated with the Use of Amphetamine, Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules, or Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sackharate, Amphetamine Sulfate Tablets

Mononydrate, Dextroampletamine Sulfate and Ampletamine Sulfate rabets The following adverse reactions have been identified during post-approval use of amphetamine, dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine aspartate monohydrate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate asbits. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency of establish a causal relationship to drug exposure. Cardiovascular

Palpitations. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use.

#### Central Nervous System

Psychotic episodes at recommended doses, overstimulation, restlessness, irritability, euphoria, dyskinesia, dysphoria, depression, tremor, tics, aggression, anger, logorrhea, dermatiliomania, paresthesia (including formication), and bruxism.

Eye Disorders

Vision blurred, mydriasis. Gastrointestinal

Unpleasant taste, constipation, other gastrointestinal disturbances.

#### Allergic

Urticaria, rash, hypersensitivity reactions including angioedema and anaphylaxis. Serious skin rashes, including Stevens-Johnson Syndrome and toxic epidermal necrolysis have been reported.

Endocrine

Impotence, changes in libido, frequent or prolonged erections.

<u>Skin</u> Alopecia,

Vascular Disorders

Raynaud's phenomenon.

Musculoskeletal and Connective Tissue Disorders Rhabdomvolvsis

Kilabuoiliyoiys

### 7 DRUG INTERACTIONS

### 7.1 Clinically Important Interactions with Amphetamines

Monoamine Ox	idase Inhibitors (MAOIs)
Clinical Impact	Concomitant use of MAOIs and CNS stimulants can
chinearmpace	sause hypertensive crisis. Potential outcomes include
	death, stroke, myocardial infarction, aortic dissection,
	ophthalmological complications, eclampsia, pulmonary
	edema, and renal failure.
Intervention	Do not administer dextroamphetamine saccharate,
	amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules concomitantly or within 14
	days after discontinuing MAOI [see Contraindications
	(4).
Examples	selegiline, tranylcypromine, isocarboxazid, phenelzine,
-	linezolid, methylene blue
Serotonergic D	
Clinical Impact	The concomitant use of dextroamphetamine saccharate,
	amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules and serotonergic drugs
	increases the risk of serotonin syndrome.
Intervention	Initiate with lower doses and monitor patients for signs
	and symptoms of serotonin syndrome, particularly
	during dextroamphetamine saccharate, amphetamine
	aspartate monohydrate, dextroamphetamine sulfate and
	amphetamine sulfate extended-release capsules initiation
	or dosage increases. If serotonin syndrome occurs,
	discontinue dextroamphetamine saccharate, amphetamine aspartate monohydrate,
	dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules and the concomitant
	serotonergic drug(s) [see Warnings and Precautions
	(5.6)].
Examples	selective serotonin reuptake inhibitors (SSRI), serotonin
	norepinephrine reuptake inhibitors (SNRI), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol,
	tricyclic antidepressants, fentanyl, lithium, tramadol,
	tryptophan, buspirone, St. John's Wort
CYP2D6 Inhibit	The concomitant use of dextroamphetamine saccharate,
Clinical Impact	amphetamine aspartate monohydrate,
	dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules and CYP2D6 inhibitors may
	increase the exposure of dextroamphetamine
	saccharate, amphetamine aspartate monohydrate,
	dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules compared to the use of the
last ann an tha a	drug alone and increase the risk of serotonin syndrome.
Intervention	Initiate with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly
	during dextroamphetamine saccharate, amphetamine
	aspartate monohydrate, dextroamphetamine sulfate and
	amphetamine sulfate extended-release capsules initiation
	and after a dosage increase. If serotonin syndrome
	occurs, discontinue dextroamphetamine saccharate,
	amphetamine aspartate monohydrate,
	dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and the CYP2D6 inhibitor [see
	Warnings and Precautions (5.6) and Overdosage (10)].
Examples	paroxetine and fluoxetine (also serotonergic drugs),
P	quinidine, ritonavir
Alkalinizing Age	
Clinical Impact	Increase blood levels and potentiate the action of
	amphetamine.
Intervention	Co-administration of dextroamphetamine saccharate,
	amphetamine aspartate monohydrate,
	dextroamphetamine sulfate and amphetamine sulfate
	extended-release capsules and gastrointestinal or urinary alkalinizing agents should be avoided.
Examples	Gastrointestinal alkalinizing agents (e.g., sodium
examples	bicarbonate), Urinary alkalinizing agents (e.g.,
	acetazolamide, some thiazides).
Acidifying Ager	
Clinical Impact	Lower blood levels and efficacy of amphetamines.
Intervention	Increase dose based on clinical response.
Examples	Gastrointestinal acidifying agents (e.g., guanethidine, reserpine, glutamic acid HCl, ascorbic acid). Urinary
	reserpine, glutamic acid HCl, ascorbic acid). Urinary
	acidifying agents (e.g., ammonium chloride, sodium acid
	phosphate, methenamine salts).
Tricyclic Antide	pressants
Clinical Impact	May enhance the activity of tricyclic or sympathomimetic
	agents causing striking and sustained increases in the concentration of d-amphetamine in the brain;
	cardiovascular effects can be potentiated.
l	······

Intervention	Monitor frequently and adjust or use alternative therapy based on clinical response.
Examples	desipramine, protriptyline
Proton Pump	Inhibitors
Clinical Impact	Time to maximum concentration (T <sub>max</sub> ) of amphetamine is decreased compared to when administered alone.
Intervention	Monitor patients for changes in clinical effect and adjust therapy based on clinical response.
Examples	omepraxole

#### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

### Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy. Registry for Psychostimulants at 1-866-961-2388 or visiting online at https://womensmentahealth.org/clinical-and-research-programs/pregnancyregistry/othermedications/.

#### Risk Summarv

Available data from published epidemiologic studies and postmarketing reports on use of prescription amphetamine in pregnant women have not identified a drug-associated risk of major birth defects and miscarriage (see Data). Adverse pregnancy outcomes, including premature delivery and low birth weight, have been seen in infants born to mothers taking amphetamines during pregnancy (see *Clinical Considerations*).

mothers taking amphetamines during pregnancy (see Clinical Considerations). No apparent effects on morphological development were observed in embryo-fetal development studies, with oral administration of amphetamine to rats and rabbits during organogenesis at doses 2 and 12 times, respectively, the maximum recommended human dose (MRHD) of 20 mg/dar gyten to adolescents, on a mg/m<sup>2</sup>basis. However, in a pre- and post-natal development study, amphetamine (*d*-to *I* ratio of 3:1) administered orally to pregnant rats during gestation and lactation caused a decrease in pup survival and a decrease in pup body weight that correlated with a delay in developmental landmarks at clinically relevant doses of amphetamine. In addition, adverse effects on reproductive performance were observed in pups whose mothers were treated with amphetamine. Long-term neurochemical and behavioral effects have also been reported in animal developmental studies using clinically relevant doses of amphetamine. (*see Data*). Data)

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, boss, or other adverse outcomes. In the U.S. general population, the estimated background risk of of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

### Clinical Considerations

### Fetal/Neonatal Adverse Reactions

Ampletamines, such as dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-releas capsules, cause vasoconstriction and thereby may decrease placental perfusion. In addition, amphetamines can stimulate uterine contractions, increasing the risk of premature delivery. Infants born to mothers taking amphetamines during pregnancy have an increased risk of premature delivery and low birth weight.

Monitor infants born to mothers taking amphetamines for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive drowsiness.

#### Data Animal Data

Animal Data Amphetamine (d- to I- ratio of 3:1) had no apparent effects on embryofetal morphological development or survival when orally administered to pregnant rats and rabbits throughout the period of organogeness is a doese of up to 6 and 16 mg/kg/day, respectively. These doese are approximately 2 and 12 times, respectively, the maximum recommended human dose (MRHD) of 20 mg/kg/day given to adolescents, on a mg/m<sup>2</sup> basis. Fetal maformations and death have been reported in mice following parenteral administration of *d*-amphetamine doses of 50 mg/kg/day (approximately 10 times the MRHD given to adolescents on a mg/m<sup>2</sup> basis) or greater to pregnant animals. Administration of these doses was also associated with severe maternal toxicity.

Administration of these doses was also associated with severe maternal toxicity. A study was conducted in which pregnant rats received daily oral doses of amphetamine (d- to *l*-mantiomer ratio of 3:1of 2, 6, and 10 mg/kg from gestation day 6 to lactation day 20. These doses are approximately 0.8, 2, and 4 times the MHHD of 20 mg/day given to adolescents, on a mg/m<sup>2</sup> basis. All doses caused hyperactityh and decreased weight gain in the dams. A decrease in pup survival was seen at all doses. A decrease in pup bodyweight was seen at 6 and 10 mg/kg on day 22 postpartum but not at 5 weeks postbeaning. When pups were tested for reproductive performance at maturation, gestational weight gain, number of implantations, and number of delivered pups were decreased in the group whose mothers had been given 10 mg/kg.

A number of studies from the literature in rodents indicate that prenatal or early postnatal exposure to amphetamine (*d*. or *d*, *l*-), at doses similar to those used clinically, can result in long-term neurochemical and behavioral alterations. Reported behavioral effects include learning and memory deficits, altered locomotor activity, and changes in sexual function

#### 8.2 Lactation

Risk Summary

The solution of the set of the s

#### 8.4 Pediatric Use

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are indicated for use in children 6 years of age and older.

The safety and efficacy of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in children under 6 years of age have not been studied. Long-term effects of amphetamines in children have not been well established.

### Long-Term Growth Suppression

Growth should be monitored during treatment with stimulants, including dextroamphetamine saccharate, amphetamine supartate monohydrate, dextroamphetamine sulfate and amphetamine suffate extended-release capsules, and pediatric patients aged 6 to 17 years who are not growing or gaining weight as expect may need to have their treatment interrupted [see Warnings and Precautions (5.3)]. -ted

#### Juvenile Animal Toxicity Data

Juvenier ats treated with mixed amphetamine saits early in the postnatal period through sexual maturation demonstrated transient changes in motor activity. Learning and memory was impaired at approximately 6 times the maximum recommended human dose (MRHD) given to children on a mg/m²basis. No recovery was seen following a drug free period. A delay in sexual maturation was observed at a dose approximately 6 times the MRHD given to children on a mg/m²basis, although there was no effect on fertility.

In a juvenile developmental study, rats received daily oral doses of amphetamine (d to l In a juvenile developmental study, rats received daily oral doses of amphetamine (d to 1 enantomer ratio of 3:1, of 2, 6, or 20 mg/kg on days 7-13 of age; from day 14 to approximately day 60 of age these doses were given b.i.d. for total daily doses of 4, 12, or 40 mg/kg. The latter doses are approximately 0.6, 2, and 6 times the MRHD of 30 mg/day, given to children on a mg/m<sup>2</sup> basis. Post dosing hyperactivity was seen at all doses; motor activity measured prior to the daily dose was decreased during the dosing period but the decreased motor activity was largely absent after an 18 day drug-free recovery period. Performance in the Morris water maze test for learning and memory was impaired at the 40 mg/kg dose, and sporadically at the lower doses, when measured prior to the daily dose during the tereatment period. A dray drug-free priod. A delay in the devental milestones of vaginal opening and preputial separation was seen at 40 mg/kg but there was no effect on

#### fertility

#### 8.5 Geriatric Use

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules have not been studied in the geratric population.

#### 8.6 Renal Impairment

Due to reduced clearance of amphetamines in patients with severe renal impairment (GFR 15 to < 30 mL/min(1.73m<sup>2</sup>), the recommended dose should be reduced. Dextroamphetamine sacrharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release recommended in patients with ESRD (GFR < 15 mL/min/1.73m²) [see Dosage and Administration (2.5) and Clinical Pharmacology (12.3)]. d-Amphetamine is not dialyzable.

#### 9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules contains amphetamine, a Schedule II controlled substance.

#### 9.2 Abuse

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are a CNS stimulant that contains amphetamine, which has a high potential for abuse. Abuse is characterized by impaired control of drug use, compulsive use despite harm, and craving.

Signs and symptoms of amphetamine abuse may include increased heart rate, respiratory rate, blood pressure, and/or sweating, dlated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostliky, aggression, suicklal or homicidal ideation have also been observed. Abusers of amphetamines may use other unapproved routes of administration which can result in overdose and death [see Overdosage (10)].

To reduce the abuse of CNS stimulants, including dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capusles, assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and proper storage and disposal of CNS stimulants. Monitor for signs of abuse while on therapy and re-evaluate the need for dextroamphetamine saccharate, sumphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules use.

#### 9.3 Dependence

Tolerance (a state of adaptation in which exposure to a specific dose of a drug results in a reduction of the drug's desired and/or undesired effects over time, in such a way that a higher dose of the drug is required to produce the same effect that was once obtained at a lower dose) may occur during chronic therapy of CNS stimulants including dextroamphetamine sucharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules,

Dysical Dependence (which is manifested by a which avail syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) may occur in patients treated with CNS stimulants including destroamphetamine saccharate, amphetamine aspartate monohydrate, destroamphetamine suffate and amphetamine suffate extended-release capsules, Withdrawal symptoms after abrupt cessation of CNS stimulants include dysphoric modd; fatigue; vivid, unpleasant dreams; insomnia or hypersonnia; increased appetite; and psychomotor retardation or agitation.

#### 10 OVERDOSAGE

LU OVERDUSAGE Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assautiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Serotonin syndrome has been reported with amphetamine use, including dextroamphetamine saccharate, amphetamine suprate tended-release capsules. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

#### Treatment

Consult with a Certified Poison Control Center for up to date guidance and advice. The prolonged release of mixed amphetamine salts from dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules should be considered when treating patients with overdose.

d-Amphetamine is not dialyzable.

#### 11 DESCRIPTION

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules contain mixed salts of a single-entity amphetamine, a CNS stimulant. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules contains equal amounts (by weight) of four salts: dextroamphetamine (DL)-aspartate monohydrate. This results in a 3.1:1 mixture of dextro- to levo- amphetamine base equivalent.

The 5 m, 10 m, 15 m, 20 m, 25 m, and 30 m, strength extended release capsules are for oral administration. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suifate and amphetamine suifate extended -release capsules contains two types of drug-containing beads (immediate-release and delayed release) which prolong the release of amphetamine aspartate monohydrate, dextroamphetamine suifate and amphetamine aspartate monohydrate, dextroamphetamine suifate and amphetamine suifate capsules (immediate-release) tablet formulation.

Fach capsule contains:

Capsule Strength:	5 mg	10 mg	15 mg	20 mg	25 mg	30 mg
Dextroamphetamine Saccharate	1.25 mg	2.5 mg	3.75 mg	5.0 mg	6.25 mg	7.5 mg
Amphetamine (D,L) Aspartate Monohydrate	1.25 mg	2.5 mg	3.75 mg	5.0 mg	6.25 mg	7.5 mg
Dextroamphetamine Sulfate	1.25 mg	2.5 mg	3.75 mg	5.0 mg	6.25 mg	7.5 mg
Amphetamine Sulfate	1.25 mg	2.5 mg	3.75 mg	5.0 mg	6.25 mg	7.5 mg
Total amphetamine base equivalence	3.1 mg	6.3 mg	9.4 mg	12.5 mg	15.6 mg	18.8 mg
d -amphetamine base equivalence	2.4 mg	4.7 mg	7.1 mg	9.5 mg	11.9 mg	14.2 mg
I -amphetamine base equivalence	0.75 mg	1.5 mg	2.3 mg	3.0 mg	3.8 mg	4.5 mg

#### Inactive Ingredients and Colors

The inactive interstant cours in the course of the interstant of the interstep interstant of the interst

The 5 mg capsule additionally includes: yellow iron oxide, red iron oxide, FD&C Blue No. 1, and FD&C Red No. 3.

The 10 mg capsule additionally includes: FD&C Blue No. 1 and FD&C Red No. 3

The 15 mg capsule additionally includes: FD&C Blue No. 1 and FD&C Red No. 3.

The 20 mg capsule additionally includes: yellow iron oxide and red iron oxide.

The 25 mg capsule additionally includes: yellow iron oxide and red iron oxide.

Additionally, the capsule imprint ink may include: shellac, propylene glycol, black iron oxide, potassium hydroxide, FD&C Blue No. 2, FD&C Red No. 40, D&C Yellow No. 10, and FD&C Blue No. 1.

#### 12 CLINICAL PHARMACOLOGY

#### 12.1 Mechanism of Action

Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The mode of therapeutic action in ADHD is not known.

#### 12.2 Pharmacodynamics

Amphetamines block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

#### 12.3 Pharmacokinetics

12.3 Pharmacokinetics
Pharmacokinetics studies of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules have been conducted in healthy aduk and pediatric (children aged 6-12 yrs) subjects, and adolescent (13-17 yrs) and children with ADHD. Both dextroamphetamine sulfate and amphetamine sulfate monohydrate, dextroamphetamine sulfate and amphetamine sulfate intendieta-release) tablets and dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate (mediate-release) tablets and dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate and amphetamine asplus contain d-amphetamine and Lamphetamine sals in the ratio of 3:1. Following administration of dextroamphetamine sulfate and amphetamine sulfate intervention for dextroamphetamine sulfate and amphetamine sulfate intervention of dextroamphetamine sulfate and amphetamine sulfate intervention of dextroamphetamine sulfate and amphetamine sulfate into of 3:1. Following administration of dextroamphetamine sulfate and amphetamine sulfate into of a sulfate into a sulfate into a sulfate into a sulfate into a sulfate release), the peak plasma concentrations occurred in about 3 hours for both d-amphetamine and l-amphetamine.

hours too both carbon plasma concentration ( $\tau_{max}$ ) for dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate ended release capaules is about 7 hours, which is about 4 hours longer compared to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate tablets (immediate-release). This is consistent with the extended-release capau.

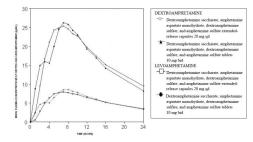


Figure 1 Mean d-amphetamine and I-amphetamine Plasma Concentrations Following Administration of Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Extended-Release Capsules 20 mg (8 am) and Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets (immediate-release) 10 mg Twice Daily (8 am and 12 noon) in the Fed State.

Daily (os ani and 12 moon) in the red state. A single does of dextroamphetamine saccharete, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release 20 mg capsules provided comparable plasma concentration profiles of both d-amphetamine and I-amphetamine to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate tablets (immediate-release) 10 mg twice daily administered 4 hours apart.

The mean elimination half-life for d-amphetamine is 10 hours in adults; 11 hours in adolescents aged 13-17 years and weighing less than or equal to 75 kg/165 Bb; and 9 hours in children aged 6 to 12 years. For the Lamphetamine, the mean elimination half-life in adults is 13 hours; 13 to 14 hours in adolescents; and 11 hours in children aged 6 to 12 years. On a mg/kg body weight basis, children have a higher clearance than adolescents or adults (see Special Populations below).

### Dextroamphetamine saccharate, amphetamine aspartate monohydrate dextroamphetamine sulfate and amphetamine sulfate extended-release capsules dexition on proceeding of the analysis of the data and the second of the data and t

Food does not affect the extent of absorption of d-amphetamine and l-amphetamine Food does not affect the extent of absorption of d-amphetamine and I-amphetamine, but prolongs Tmax by 2.5 hours (from 5.2 hrs at fasted state to 7.1 hrs after a high-fat meal) for d-amphetamine and 2.7 hours (from 5.6 hrs at fasted state to 8.3 hrs after a high fat meal) for I-amphetamine after administration of dextroamphetamine ascharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules 30 mg. Opening the capsule and sprinkling the contents on applesauce results in comparable absorption to the intact capsule taken in the fasted state. Equal doses of dextroamphetamine sucharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine extended-release capsules strengths are bioequivalent.

#### Metabolism and Excretion

Metabolism and Excretion Amphetamine is reported to be oxidized at the 4 position of the benzene ring to form 4-hydroxyamphetamine, or on the side chain  $\alpha$  or  $\beta$  carbons to form alpha-hydroxy-amphetamine or norephedrine, respectively. Norephedrine and 4-hydroxy-amphetamine are both active and each is subsequently oxidized to form 4-hydroxy-norephedrine. Alpha-hydroxy-amphetamine undergoes deamination to form henylacetone, which ultimately forms benzoic acid and ts glucuronide and the glycine conjugate hippur's acid. Although the enzymes involved in amphetamine metabolism have not been clearly defined, CYP2D6 is genetically polymorphic, population variations in amphetamine metabolism are a possibility.

Ampletamine is known to inhibit monoamine oxidase, whereas the ability of amphetamine and its metabolites to inhibit various P450 isozymes and other enzymes has not been adequately elucitated. *In vitro* experiments with human microsomes indicate minor inhibition of CYP2D6 by amphetamine and minor inhibition of CYP1A2, 206, and 3A4 by one or more metabolites. However, due to the probability of auto-inhibition and the lack of information on the concentration of these metabolites relative inhibition and concentration of these metabolites. to *in vivo* concentrations, no predications regarding the potential for amphetamine or its metabolites to inhibit the metabolism of other drugs by CYP isozymes *in vivo* can be made.

made. With normal urine pHs, approximately half of an administered dose of amphetamine is recoverable in urine as derivatives of alpha-hydroxy-amphetamine and approximately another 30 to 40% of the dose is recoverable in urine as amphetamine has a pKa of 9.9, urinary recovery of amphetamine highly dependent on pH and urine flow rates. Akaline urine pHs result in less ionization and reduced renal elimination, and acidic pHs and high flow rates result in increased renal elimination with clearances greater than glomerular filtration rates, indicating the involvement of active sceretion. Urinary recovery of amphetamine has been reported to range from 1% to 75%, depending on urinary pH, with the remaining fraction of the dose hepatically metabolized. Consequently, both hepatic and real dysfunction have the potential to inhibit the elimination of amphetamine and result in prolonged exposures. In addition, and decrease in amphetamine's metabolism that might occur due to drug interactions or genetic polymorphism is more likely to be clinically significant when renal elimination is decreased [see Drug Interactions (7)]. Snerial Ponulations

#### Special Populations

Comparison of the pharmacokinetics of d- and Lamphetamine after oral administration Comparison of the phanacokinetics of 0- and i-ampinedmine arter or al administration of dextroamphetamine sacharate, amphetamine aspariate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in children (6-1 years) and adolescent (13-17 years) ADHD patients and heakhy adu volunteers indicates that body weight is the primary determinant of apparent differences in the pharmacokinetics of 4- and 1-amphetamine across the age range. Systemic exposure measured by area under the curve to infinity (AUC<sub>w</sub>) and maximum plasma concentration ( $C_{maxl}$ ) decreased with increases in body weight, while oral volume of distribution (V<sub>L</sub>F), oral clearance (CL/F), and elimination half-life ( $t_{1/2}$ ) increased with increases in body weight.

#### Pediatric Patients

To an angkg weight basis, children eliminated amphetamine faster than adults. The elimination half-life (t<sub>122</sub>) is approximately 1 hour shorter for d-amphetamine and 2 hours shorter for tamphetamine in children than in adults. However, children had higher systemic exposure to amphetamine ( $C_{max}$  and AUC) than adults for a given dose of dextroamphetamine suchareate, amphetamine sufface schendel -release capsules, which was attributed to the higher dose administered to children on a mg/kg body weight basis compared to adults. Upon dose normalization on a mg/kg basis, children showed 30% less systemic exposure compared to adults.

#### Gender

Systemic exposure to amphetamine was 20 to 30% higher in women (N=20) than in men (N=20) due to the higher dose administered to women on a mg/kg body weight basis. When the exposure parameters ( $C_{max}$  and AUC) were normalized by dose (mg/kg), these differences diminished. Age and gender had no direct effect on the pharmacokinetics of d- and l-amphetamine.

#### Race

Formal pharmacokinetic studies for race have not been conducted. However, amphetamine pharmacokinetics appeared to be comparable among Caucasians (N=33), Blacks (N=8) and Hispanics (N=10).

#### Patients with Renal Impairment

The effect of renal impairment on d- and Lamphetamine after administration of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules has not been studied. The impact of renal impairment on the disposition of amphetamine is expected to be similar between oral administration of lisdexamphetamine and dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

In a pharmacokinetic study of Isdexamphetamine in adult subjects with normal and impaired renal function, mean d-amphetamine clearance was reduced from 0.7 L/hr/kg in normal subjects to 0.4 L/hr/kg in subjects with severe renal impairment (GFR 15 to < 30 mL/min/.7 3m<sup>2</sup>). Dialysis did not significantly affect the clearance of d-amphetamine [see Use In Specific Populations (8.6)].

#### 13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

#### Carcinogenesis

No evidence of carcinogenicity was found in studies in which *d*, *i*-amphetamine (enantiomer ratio of 1:1) was administered to mice and rats in the diet for 2 years at doses of up to 30 mg/kg/day in male mice, 19 mg/kg/day in female mice, and 5 mg/kg/day in male and female rats. These doses are approximately 2.4, 1.5, and 0.8 times, respectively, the maximum recommended human dose for children of 30 mg/day given to children, on a mg/m<sup>2</sup> basis.

#### Mutagenesis

Ampletamine, in the enantiomer ratio d- to I-ratio of 3:1, was not clastogenic in the mouse bone marrow micronucleus test *in vivo* and was negative when tested in the *E*. coli component of the Ames test *in vito*. Al-Ampletamine (1:1 enantomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucle test, an equivacal response in the Ames test, and negative responses in the *in vitro* sister chromatid exchange and chromosomal aberration assays.

#### Impairment of Fertility

Amphetamine, in the enantiomer d- to I-ratio of 3:1, did not adversely affect fertility or early embryonic development in the rat at doses of up to 20 mg/kg/day (approximately times the maximum recommended human dose for adolescents of 20 mg/day, given to adolescents, on a mg/m<sup>2</sup> body surface area basis). lv 8

#### 13.2 Animal Toxicology and/or Pharmacology

Acute administration of high doses of amphetamine (d- or d,l-) has been shown to produce long-lasting neurotoxic effects, including irreversible nerve fiber damage, in rodents. The significance of these findings to humans is unknown.

#### 14 CLINICAL STUDIES

#### Pediatric Patients

<u>Pediatric Patients</u> A double-bilind, randomized, placebo-controlled, parallel-group study was conducted in children aged 6 to 12 (N=584) who met DSM-IV® criteria for ADHD (either the combined type or the hyperactive- impulsive type). Patients were randomized to fixed-does treatment groups receiving final does so 10, 20, or 30 mg of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules or placebo once daily in the morning for three weeks. Significant improvements in patient behavior, based upon teacher ratings of attention and hyperactivity, were observed for all dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release compared to patients who received placebo, for all three weeks, including the first week of tratement, when al dextroamphetamine suffate extended-release capsules subjects were receiving a dose of 10 mg/day. Patients who received dextroamphetamine sulfate extended-release capsules showed behavioral improvements in both morning and alternoon assessments compared to patients on placebo.

In a classroom analogue study, patients (N=51) receiving fixed doses of 10 mg, 20 mg or 30 mg dextroamphetamine saccharate, amphetamine aspartate monohydrate dextroamphetamine sulfate and amphetamine sulfate extended-release capsules demonstrated statistically significant improvements in teacher-rated behavior and performance measures, compared to patients treated with placebo.

demonstrated statistically significant improvements in teach-rated behavior and performance measures, compared to patients treated with placebo. A double-blind, randomized, multi-center, parallel-group, placebo-controlled study was conducted in adolescents aged 13 to 17 (N=327) who met DSM-V<sup>6</sup> criteria for ADHD. The primary cohort of patients (n=287, weighing  $\leq$  75 kg/165 bs) was randomized to fixed-dose treatment groups and received four weeks of treatment. Patients were randomized to receive final doses of 10 mg, 20 mg, 30 mg, and 40 mg dextroamphetamine saccharate, amphetamine supfate extended-release capsules or placebo once daily in the morning. Patients randomized to fixed-dose treatment in the morning, Patients randomized to fixed-dose treatment or placebo once daily in the morning. Patients randomized to faxed-dose treatment or placebo once daily in the morning. Patients randomized to faxed-dose treatment groups are cliving final doses by 10 mg each week. The secondary cohort consisted of 40 subjects weighing > 75 kg/165 bs who were randomized to fixed-dose treatment sulfate extended-release capsules or placebo once daily in the morning for 4 weeks. The primary efficacy variable was the Attention Deficit Hyperactivity Disorder-Rating Scale IV (ADHD-K-F) to toal score for the primary cohort. The ADHD-K-Si V is an 18-tem scale that measures the core symptoms of ADHD. Improvements in the primary cohort were statistically significantly grater in all four primary cohort active treatment groups (dextroamphetamine sucharate, amphetamine suffate extended-release capsules 10 mg, 20 mg, 30 m

20 mg, 30 mg, and 40 mg) compared with the placebo group. There was not adequate evidence that doses greater than 20 mg/day conferred additional benefit.

### Adult Patients

A double-blind, randomized, placebo-controlled, parallel-group study was conducted in adults (N=255) who met DSM-IV® criteria for ADHD. Patients were randomized to fixed-dose treatment groups receiving final doses of 20, 40, or 60 mg of dextroamphetamine dose treatment groups receiving final doses of 20, 40, or 60 mg of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules or placebo once daily in the morning for four weeks. Significant improvements, measured with the Attention Deficit Hyperactivity Disorder-Rasing Scale (ADHD-RS), an 18-item scale that measures the corre symptoms of ADHD, were observed at endpoint for all dextroamphetamine sactharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate extended-release capsules doses compared to patients who received placebo for all four weeks. There was not adequate evidence that doses greater than 20 mg/day conferred additional benefit.

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

Dextroamphetamine saccharate, amphetamine aspartate monohydrate

dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are available

5 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1184' in black ink and light orange opaque body imprinted 'N' in black ink.

NDC 70710-1184-1..... ....Bottles of 100 10 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1185' in black ink and light blue opaque body imprinted 'N' in black ink.

NDC 70710-1185-1..... .....Bottles of 100

15 mg: Hard gelatin capsules with light blue opaque cap, imprinted '1186' in black ink and white opaque body imprinted 'N' in black ink.

NDC 70710-1186-1..... .....Bottles of 100 20 mg: Hard gelatin capsules with light orange opaque cap, imprinted '1187' in black ink and light orange opaque body imprinted 'N' in black ink.

NDC 70710-1187-1..... ......Bottles of 100 25 mg: Hard gelatin capsules with light orange opaque cap, imprinted '1188' in black ink and white opaque body imprinted 'N' in black ink.

NDC 70710-1188-1...... .....Bottles of 100

30 mg: Hard gelatin capsules with white opaque cap, imprinted '1189' in black ink and white opaque body imprinted 'N' in black ink.

NDC 70710-1189-1..... .....Bottles of 100 Dispense in a tight, light-resistant container as defined in the USP.

Store at 20°C to 25°C (68°F to 77° F). Excursions permitted to 15°C - 30°C (59 - 86° F) [see USP CONTROLLED ROOM TEMPERATURE].

#### Disposal

Disposal Comply with local laws and regulations on drug disposal of CNS stimulants. Dispose of remaining, unused, or expired dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules at authorized colection sites such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with an undesirable, entoxic substance to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and discard Dextroamphetamine sulfate and amphetamine sulfate extended-release capsules with rash. household trash

#### 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide). Controlled Substance Status/Potential for Abuse, Misuse, and Depen

Advise patients that dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are a federally controlled substance because it can be abused or lead to capsures are a rearraily controlled substance because it can be abused or lead to dependence. Additionally, emphasize that destroamphetamine saccharate, amphetamine aspartate monohydrate, destroamphetamine sulfate and amphetamine sulfate extended-release capsules should be stored in a safe place to prevent misuse and/or abuse. Evaluate patient history (including family history) of abuse or dependence on alcohol, prescription medicines, or lilicit drugs [see Warnings and Precautions (5.1), Drug Abuse and Dependence (9)].

#### Serious Cardiovascular Risks

Advise patients of serious cardiovascular risk (including sudden death, myocardial infarction, stroke, and hypertension) with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during treatment should undergo a prompt cardiac evaluation [see Warnings and Precautions (5.1)]. (5.1)]

#### Psychiatric Risks

Psychiatric tisks Prior to initiating treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, adequately screen patients with comorbid depressive symptoms to determine if they are at risk for bipolar disorder. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and/or depression. Additionally, dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules therapy at usual doses may cause treatment-emergent psychotic or manic symptoms in patients without prior history of psychotic symptoms or mania [see Warnings and Precautions (5.2)]. amphetamine

### Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]

Instruct patients beginning treatment with dextroamphetamine saccharate, Instruct patients beginning treatment with dextroamphetamine sarcharate, amphetamine asparate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules about the risk of peripheral vasculopathy, including Raynaud's Phenomenon, and in associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red. Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes. Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking dextroamphetamine saccharate, amphetamine sulfate extended-release capsules. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients [see Warnings and Precautions (5.5)].

#### Serotonin Syndrome

Serotonin Syndrome Caution patients about the risk of serotonin syndrome with concomitant use of dextroamphetamine saccharate, amphetamine supartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and other serotonergic drugs including SSRIs, SynBis, triptans, tricyclic antidepressants, fentamyl, lithium, tramadol, tryptophan, buspirone, SL John's Wort, and with drugs that impair metabolism of serotonin (in particular MAOIs, both those intended to treat psychiatric disorders and also others such as linezolid [see Contraindications (4), Warnings and Precautions (5.6) and Drug Interactions (7.1). Advise patients to contact their healthcare provider or report to the emergency room if they experience signs or symptoms of serotonin syndrome. symptoms of serotonin syndrome.

#### Concomitant Medications

Advise patients to notify their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs because there is a potential for interactions [see Drug Interactions (7.1)].

#### Growth

Monitor growth in children during treatment with dextroamphetamine saccharate, ampletamine aspartate monohydrate, dextroampletamine suffate and ampletamine suffate extended-release capsules, and patients who are not growing or gaining weight as expected may need to have their treatment interrupted [see Warnings and Precautions (5.3)].

### Pregnancy Registry

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules during pregnancy [see Use In Specific Populations (8.1)].

Pregnancy

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules. Advise patients of the potential fetal effects from the use of dextroamphetamine sucharate, amphetamine supartate monohydrate, dextroamphetamine suffate and amphetamine sulfate extended-release capsules during pregnancy [see Use In Specific Populations (8.1)].

#### Lactation

Advise women not to breastfeed if they are taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules [see Use In Specific Populations (8.2)]. Impairment in Ability to Operate Machinery or Vehicles

# Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.

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## For additional copies of the printed patient information/medication guide, please visit wwww.zydus.com or call 1-877-993-8779.

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#### MEDICATION GUIDE

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE and AMPHETAMINE SULFATE EXTENDED-RELEASE CAPSULES, CII

# (DEX-troe-am-FET-a-meen sak-uh-reyt, am-FET-a-meen uh-spahr-teyt mo uh-hayhy-dreyt, DEX-troe-am-FET-a-meen suhl-feyt, am-FET-a-meen suhl-feyt)

Read the Medication Guide that comes with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine sulfate extended-release capsules before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

# What is the most important information I should know about dextroamphetamine saccharate, amphetamine sapartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are a stimulant medicine. The following have been reported with use of stimulant medicines.

Heart-related problems:
 sudden death in patients who have heart problems or heart defects
 stroke and heart attack in adults
 increased blood pressure and heart rate

Tell your doctor if you or your child has any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting dextroamphetamine saccharate, amphetamine aspartate monohydrate dextroamphetamine sulfate and amphetamine sulfate extended-release capsules

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

#### 2. Mental (Psychiatric) problems:

All Patients • new or worse behavior and thought problems • new or worse bipolar illness • new or worse aggressive behavior or hostility

Children and Teenagers • new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your doctor about any mental problems you or your child has, or about a family history of suicide, bipolar illness, or depression

Call your doctor right away if you or your child has any new or worsening mental symptoms or problems while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules, especially seeing or hearing things that are not real, or are suspicious.

 Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]. Fingers or toes may feel numb, cool, painful
 Fingers or toes may change from pale, to blue, to red

## Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.

Call your doctor right away if you have or your child has any unexplained wounds appearing on fingers or toes while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

# What are dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

Dextroamphetamine saccharate, amphetamine aspartate monohydrate Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sufface tarkended-release capsules are a once daily central nervous system stimulant prescription medicine. It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Dextroamphetamine sucharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine sulfate extended-release capsules may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Dextroamphetamine saccharate, amphetamine aspartate monohydrate dextroamphetamine suffate and amphetamine suffate extended individues, dextroamphetamine suffate and amphetamine suffate extended-release capsules should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

omer merapies. Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules are a federally controlled substance (CII) because it can be abused or lead to dependence. Keep dextroamphetamine sulfate and amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place to prevent misuse and abuse. Selling or giving away dextroamphetamine saccharate, amphetamine sulfate extended-release capsules in a safe place to prevent misuse and abuse. Selling or giving away dextroamphetamine saccharate, amphetamine sulfate extended-release capsules may harm others, and is against the law.

Tell your doctor if you or your child has (or has a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

# Who should not take dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules should not be taken if you or your child: • have heart disease or hardening of the arteries

- have heart disease or hardening of the arterie have moderate to severe high blood pressure
  have hyperthyroidism
  have an eye problem called glaucoma are very anxious, tense, or agitated
  have a history of drug abuse

- are taking or have taken within the past 14 days an anti-depression medicine called a e oxidase inhibitor or MAOI
- are sensitive to, allergic to, or had a reaction to other stimulant medicines

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules have not been studied in children less than 6 years old.

not been studied in children less than 6 years old. Dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may not be right for you or your child. Before starting dextroamphetamine sulfate and amphetamine sulfate extended-release capsules ind your or your child's doctor about all health conditions (or a family history of) including if you or your child: have heart problems, heart defects, or high blod pressure have mental problems including psychosis, mania, bipolar illness, or depression have heart fourthe's wordrome

- have tics or Tourette's syndrome
- have liver problems have kidney problems
- have end stage renal disease (ESRD) have thyroid problems
- have seizures or have had an abnormal brain wave test (EEG)

- have secures or have had an abnormal brain wave test (EEG) have circulation problems in fingers and toes are pregnant or plan to become pregnant. It is not known if dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules will harm your unborn baby. There is a pregnancy registry for females who are exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules during pregnancy. The purpose of the registry is to collect information about the health of females exposed to the registry is to collect information about the health of females exposed to dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine suffate extended-release capsules and their bab, if you or your child becomes pregnant during treatment with dextroamphetamine suffate and amphetamine suffate extended-release capsules and their bab, if you or your child becomes pregnant during treatment with to your healthcare provider about registering with the National Pregnancy Registry of Psychostimulants at 1-866-961-2388 or visit online at https://womsmentameatun.org/child-and-research-programs/pregnancyregistry/othermedications/ are breastfeeding or plan to breastfeed. Dextroamphetamine suffate and amphetamine suffate extended-release capsules passes into breast mit. You or your child should not breastfeed during treatment with dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine suffate extended-release capsules passes into breast field. You or your child should not breastfeed during treatment with dextroamphetamine saccharate, amphetamine sapartate monohydrate, dextroamphetamine suffate and amphetamine aspartate monohydrate.

## Can dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and non-prescription medicines, vitamins, and herbal supplements. Dextroamphetamine sacharate, amphetamine aspartate monolydrate, dextroamphetamine suifate and amphetamine suifate extended-release capsules and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking dextroamphetamine sucharate, amphetamine aspartate monolydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.

Your doctor will decide whether dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules can be taken with other medicines.

# Especially tell your doctor if you or your child takes: anti-depression medicines including MAOIs anti-psychotic medicines

- lithium narcotic pain medicines
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- ch acid medicines stoma
- cold or allergy medicines that contain decongestants

## Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

# Do not start any new medicine while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules without talking to your doctor first.

- ampletamine subleta excelute-release capsules without taking to your doctor first.
  How should dextroampletamine saccharate, ampletamine aspartate monohydrate, dextroampletamine sulfate and ampletamine sulfate extended-release capsules be taken?
  Take dextroampletamine saccharate, ampletamine aspartate monohydrate, dextroampletamine sulfate and ampletamine sulfate extended-release capsules without taking to your doct may adjust the dose until its right for you or your child.
  Take dextroampletamine saccharate, ampletamine aspartate monohydrate, dextroampletamine sulfate and ampletamine sulfate extended-release capsules once a day in the morning when you first wake up. Dextroampletamine sulfate extended-release capsules are an extended release capsule. It releases medicine into your body throughout the day.
  Swallow dextroampletamine saccharate, ampletamine aspartate monohydrate, dextroamphetamine sulfate and ampletamine sulfate extended-release capsules whole with water or other liquids. If you or your child cannot swallow the capsule, open it and sprinkt the medicine over a spoonful of applesauce. Swallow al of the applesauce and medicine mixture without chewing immediately. Follow with a drink of water or other liquids. If you or your child cannot swallow the capsule, open it and sprinkt the redicine over a spoonful of applesauce. Swallow al of the applesauce and medicine mixture without chewing immediately. Follow with a drink of water or other liquids. If you or your child cannot swallow the day. the capsule.
- Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules can be taken with or without food.
- be taken with or without food. From time to time, your doctor may stop dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules treatment for a while to check ADHD symptoms. Your doctor may do regular checks of the blood, heart, and blood pressure while taking dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate extended-release capsules. Children should have their height and weight checked often while taking dextroamphetamine sacrate, amphetamine asmatter monohydrate. dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules.
- Dextroampletamine suitate and ampletamine suifate extended release of dextroampletamine sulfate and ampletamine sulfate extended-release of treatment may be stopped if a problem is found during these check-ups ase capsules
- If you or your child takes too much destroampletate teak epsi-if you or your child takes too much destroampletamine saccharate, amphetamine suffate extended-release capsules or overdoses, call yo doctor or poison control center right away, or get emergency treatme

# What are possible side effects of dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

See "What is the most important information I should know about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?" for information on reported heart and mental problems.

- Other serious side effects include: slowing of growth (height and weight) in children seizures, maihy in patients with a history of seizures eyesight changes or blurred vision
- Common side effects include:
- headache decreased appetite
- stomach ache nervousness
- trouble sleeping
- mood swings

- weight loss
- dizziness
  dry mouth
  fast heart beat

Dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules may affect your or your child's ability to drive or do other dangerous activities. Talk to your doctor if you or your child has side effects that are bothersome or do not

go away. This is not a complete list of possible side effects. Ask your doctor or pharmacist for

more information Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800- FDA-1088.

How should I store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

- Xtended-release capsules?
  Store dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules in a safe place at room temperature, 68°F to 77°F (20°C to 25°C).
  Keep dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules and all medicines out of the reach of children.

# General information about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suifate and amphetamine suifate extended-release capsules for a condition for which it was not prescribed. Do not give dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Ins Meakadon Gues summarkes the most important information adout dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine suffate extended-release capsules. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine suffate and amphetamine suffate extended-release capsules that was written for healthcare professionals. For more information, you may also contact Zydus Pharmaceuticals at 1-877-993-8779 or www.zydususa.com.

# What are the ingredients in dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate extended-release capsules?

Active Ingredients: dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate, USP, amphetamine sulfate, USP Inactive Ingredients: sucrose, corn starch, hydroxypropyl cellulose, methacrylic acid copolymer dispersion, tak, triethyl citrate, polyvinyl akohol, titanium dioxide, mon/diglycerides, sodium lauryl sulfate, yellow iron oxide, and red iron oxide. The capsule shells contain gelatin and titanium dioxide.

The 5 mg capsule additionally includes: yellow iron oxide, red iron oxide, FD&C Blue No. 1, and FD&C Red No. 3.

The 10 mg capsule additionally includes: FD&C Blue No. 1 and FD&C Red No. 3. The 15 mg capsule additionally includes: FD&C Blue No. 1 and FD&C Red No. 3.

The 20 mg capsule additionally includes: yellow iron oxide and red iron oxide.

The 25 mg capsule additionally includes: yellow iron oxide and red iron oxide.

Additionally, the capsule imprint ink may include: shellac, propylene glycol, black iron oxide, potassium hydroxide, FD&C Blue No. 2, FD&C Red No. 40, D&C Yellow No. 10, and FD&C Blue No. 1.

#### Manufactured By:

Nesher Pharmaceuticals USA LLC

St. Louis, MO 63044

Distributed by:

Zydus Pharmaceuticals USA Inc.

Pennington, NI 08534

P10343-3rasub 7/2019

This Medication Guide has been approved by the U.S. Food and Drug Administration

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1184-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) CII

5 mg

Pharmacist: Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals 100 CAPSULES

### Rx Only

NDC 70710-1184-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate **Extended-Release Capsules** (Mixed Salts of a Single Entity Amphetamine Product)



Medication Guide to each patient 100 CAPSULES Z zydus Rx Only

5 mg 100 count Bottle Label

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1185-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) CII

10 mg

Pharmacist: Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals 100 CAPSULES

Rx Only



10 mg 100 count Bottle Label

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1186-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) Cli

15 mg

Pharmacist: Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals

100 CAPSULES

## Rx Only

NDC 70719-1186-1 Dextroamphetamine Aspartate Amphetamine Aspartate Sulfate, Amphetamine Sulfate Sulfate, Amphetamine Sulfate Extended-Release Capsules (Marc Safe) Entry Amphetamine Product 15 mg Pharmact: Disponse the accompanying

100 CAPSULES Rx Only

15 mg 100 count Bottle Label

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1187-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) Cli

20 mg

Pharmacist: Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals 100 CAPSULES

Rx Only

#### NDC 70710-1187-1

To zydus



100 CAPSULES

Rx Only 20 mg 100 count Bottle Label

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1188-1 Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product)

CII 25 mg

Pharmacist: Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals 100 CAPSULES

Rx Only

#### NDC 70710-1188-1



25 mg 100 count Bottle Label

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70710-1189-1

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, Amphetamine Sulfate Extended-Release Capsules (Mixed Salts of a Single Entity Amphetamine Product) Cli

30 ma

**Pharmacist:** Dispense the accompanying Medication Guide to each patient. Zydus Pharmaceuticals

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tem Codd     NOSCOTORIO     NOSCOTORI     NOSCOTORIO     NOSC	and in a Boo	TTLE: Type 0: Not a Cor tion ation Number or M Citation BBO MINE SACCHA EXTROAMPHE LFATE INTER, amphetamine Ifate capsule, exter MUMAI PRESCRIPTIC ORAL CORL	nbination 1 onograph RATE, A TAMINE aspartate n nded releas N Rereas N IZPV62004) AMINE - NE: RFW2ET67 (1:1) TYPE 4 0)	I L2/31/201 Marke SULL nonohyce e n Code ( Schedu Schedu AMP More Salu Sull Nore Salu Sull Nore Salu Sull Sull Sull Sull Sull Sull Sull	ate bate Date	Mark	eting End Date End E.70710-11 2.5 mg 2.5 mg 2.5 mg 2.5 mg
tem Codd.     NO.270710-     INST-0710-     IN	and in a Boo	ITTLE: Type 0: Not a Cor tion ation Number or M Citation B00 IINE SACCHA EXTROAMPHE LFATE INE SACCHA INE	nbination 1  nonograph  RATE, A  RATE, A  RATE, A  RATE, A  Sapartate n  ded releas  N  Rer  DEA  073)  L2 PV62004)  AMINE -  N  N  Rer  12 PV62004)  AMINE -  13 AMINE -  14	I L2/31/201 Marke SULL nonohyce e n Code ( Schedu Schedu AMP More Salu Sull Nore Salu Sull Nore Salu Sull Sull Sull Sull Sull Sull Sull	ate bate Date Date Date Source) FATE ANN FATE AN	Mark	
tem Codd.     NOLVERIAL     Nounce Section	and in a Boo	TTLE: Type 0: Not a Cor tion ation Number or M Citation B0 B0 B0 B1NE SACCHA EXTROAMPHE EXTROAMPHE EXTROAMPHE INTE SACCHA INTE SACCHA EXTROAMPHE EXTROAMPHE INTE COPULATION B1/200 B1	nbination 1  nonograph  RATE, A  RATE, A  RATE, A  RATE, A  Sapartate n  ded releas  N  Rer  DEA  073)  L2 PV62004)  AMINE -  N  N  Rer  12 PV62004)  AMINE -  13 AMINE -  14	I LIZIZI ALA CALLER AND A LIZIZIZI ALA CALLER AND A LIZIZI ALA CALLER AND A LI	ate bate Date Date Date Source) FATE ANN FATE AN	Mark	
tem Codd.     NOLVERIAL     Nounce Section	abo in 1 Boo product BO and December 2012 and De	TTLE: Type 0: Not a Cor tion ation Number or M Citation B0 B0 B1NE SACCHA EXTROAMPHE EXTROAMPHE EXTROAMPHE INTE SACCHA EXTROAMPHE EXTROAMPHE INTE SACCHA B1ACCHA	nbination 1 nonograph RATE, A TAMINE aspartate n ded releas N Rer 073) 12PV62004) AMINE - NII: RYYTYE A 100) 12PV62004 AMINE - 12PV62004 1	I LIZIJIZOI	ate bate Date Date Date Source) FATE ANN FATE AN	ASPA ampheta ampheta Rength INNE FATE	

DEXTROAMPHETAMINE SACCHARATE, AMPHETAMINE ASPARTATE MONOHYDRATE, DEXTROAMPHETAMINE SULFATE AND AMPHETAMINE SULFATE

Product Inform Product Type Route of Administ Active Ingredie DEXTROAMPIETAME DEXTROAMPIETAME DEXTROAMPIETAME DEXTROAMPIETAME DEXTROAMPIETAME SUBJINICEASING INACCASINACCASING INACCASING INACCASINACCASINACCASINACCASING IN	nation tration nt/Active Ingred	fate capsule, extende				
Route of Administ Active Ingredie DEXTROAMPHETAM DEXTROAMPHETAM DEXTROAMPHETAMIS MAPHETAMINE - UNIT DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMINE MAPHETAMINE - UNIT Inactive Ingred HYDROXYPROPYL C	nt/Active Ingred	DRUG	ltem (			
Active Ingredie DEXTROAMPHETAMIN DEXTROAMPHETAMIN MAPHETAMINE ASPN DEXTROAMPHETAMIN DEXTROAMPHETAMINE DEXTROAMPHETAMINE SULINECKB33KGX7E) Inactive Ingred HYDROXYPROPYL C	nt/Active Ingred	ORAL		Code (Source)	ND	C:70710-118
DESTROAMPHETAM DEXTROAMPHETAMINE AMPHETAMINE AU DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE MICKB33KGX7E) INICKB33KGX7E) INICKB33KGX7E) INICKB34KGX7E	Ingred		DEA S	chedule	CII	
DESTROAMPHETAM DEXTROAMPHETAMINE AMPHETAMINE AU DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE DEXTROAMPHETAMINE MICKB33KGX7E) INICKB33KGX7E) INICKB33KGX7E) INICKB34KGX7E	Ingred	Moiety				
AMPHETAMINE ASP AMPHETAMINE - UNIE DEXTROAMPHETAMINE DEXTROAMPHETAMINE SULI MAPHETAMINE SULI INIECK833KGX7E) INIECK833KGX7E) INIECK833KGX7E INIECK83KGX7E		lient Name		Basis of Str		Strengt
AMPHETAMINE - UNI: DEXTROAMPHETAMI DEXTROAMPHETAMINE SULI MILCK833KGX7E) INACTIVE INGRED INGROXYPROPYL C METHACRYLIC ACID		UOSIFI) NOHYDRATE (UNII: 01ZP)		SACCHARATE AMPHETAMINE ASP		3.75 mg
INICCESSION OF THE SULT INICCESSION OF THE SULT INICCESSION OF THE SULT INICCESSION OF THE SULT OF THE SULT INICCESSION OF THE SULT OF THE	CK833KGX7E	) E (UNII: 117680327N)		MONOHYDRATE DEXTROAMPHETAM		3.75 mg
HYDROXYPROPYL C		U051FI) DPV8NK46S) (AMPHETAMIN	ίΕ -	SULFATE AMPHETAMINE SUL	FATE	3.75 mg
HYDROXYPROPYL C						
METHACRYLIC ACID		Ingredient Nan				Strengt
	-ETHYL ACR	YLATE COPOLYMER (1:)				
STARCH, CORN (UNII	I: 08232NY35	FIED (UNII: 532859j990) 5j)				
SUCROSE (UNII: C15: TALC (UNII: 75EV7)4R	1U)					
RIETHYL CITRATE						
Product Charac	teristics					
	HITE (white)	, BLUE (light blue)		Score		o score Bmm
lavor				Imprint Code	1	186;N
ontains						
Packaging						
# Item Code		ckage Description		larketing Start Date	Marke	eting End Date
1186-1 F	Product	ree, rype o. Not a combin	12/3	31/2016		
Marketing Ir	oformat	ion				
Marketing Category		tion Number or Mono Citation	graph	Marketing Start Date	Mark	eting End Date
INDA	ANDA21008		1	2/30/2016		
EXTROAMP	НЕТАМ	INE SACCHARA	TE, AM	PHETAMINE	ASPA	RTATE
MONOHYDRA MPHETAMI	ATE, DE	XTROAMPHETA	MÍNES	SULFATE ANI	D	
extroamphetamir	ne sacchara	ate, amphetamine asp		nohydrate, dextro	ampheta	mine
		fate capsule, extende	a release			
Product Inform	ation	HUMAN PRESCRIPTION				
Product Type Route of Administ	tration	DRUG		Code (Source) chedule		C:70710-118
Active Ingredie						
DEXTROAMPHETAM	INE SACCHA	lient Name RATE (UNII: G83415V073) U051FI)		Basis of Str DEXTROAMPHETAM SACCHARATE		Strengt 5 mg
	ARTATE MOI	NOHYDRATE (UNII: 01ZP)		AMPHETAMINE ASP MONOHYDRATE		5 mg
DEXTROAMPHETAM DEXTROAMPHETAMIN	E - UNII:TZ 47	E (UNII: JJ7680327N) U051FI) iDPV8NK46S) (AMPHETAMIN		DEXTROAMPHETAM	IINE	5 mg
JNII:CK833KGX7E)	ATE (UNII: 0	ICPV8NK405) (AMPRETAMIN	IE -	AMPHETAMINE SUL	FATE	5 mg
nactive Ingred	ients					
		Ingredient Nan 1600000 WAMW) (UNII:	RFW2ET671P			Strengt
		FIED (UNII: 532859J990)	I) TYPE A (U	JNII: NX76LV5T8J)		
STARCH, CORN (UNII SUCROSE (UNII: C15)	1H8M554)	5J)				
TALC (UNII: 75EV7J4R		/2JP)				
RIETHYL CITRATE	(UNII: 8Z96Q)	XD6UM)				
Product Charac	teristics					
Color ORAN Shape CAPS		inge) , ORANGE (light oran	ge)	Score		no score 18mm
lavor				Imprint Co	ode	1187;N
Jontains						
Packaging						
# Item Code		ckage Description		larketing Start Date	Магке	eting End Date
	Product		12/3	31/2016		
	format	ion				
Marketing II		tion Number or Mono Citation	graph	Marketing Start Date	Mark	eting End Date
Marketing	ANDA21008		1	2/30/2016		
Marketing Category			TE 4.84		ACDA	
Marketing Category INDA	LETAM	XTROAMPHETA				NIAIE
Marketing Category INDA DEXTROAMP	ATE, DE			nohydrate deytro	ampheta	
Marketing Category NDA DEXTROAMP AONOHYDRA AMPHETAMII extroamphetamir	ATE, DE NE SUL	FATE ate, amphetamine asp		nonjulace, aexalo		mine
Marketing Category NDA DEXTROAMP AONOHYDRA AMPHETAMII extroamphetamir	ATE, DE NE SUL	FATE		nonjurute, uexito		mine
Marketing Category NDA DEXTROAMP AONOHYDRA MPHETAMII extroamphetamir ulfate and amphe Product Inform	ATE, DE NE SULI ne sacchara tamine sul	FATE ate, amphetamine asp fate capsule, extende	d release			
Marketing Category NRDA DEXTROAMP MONOHYDRA MOPHETAMII extroamphetamii ulfate and amphe Product Inform Product Type	ATE, DE NE SULI ne sacchara nation	FATE ate, amphetamine asp	d release Item C	Code (Source)		
Marketing Category NRDA DEXTROAMP MONOHYDRA MOPHETAMII extroamphetamii ulfate and amphe Product Inform Product Type	ATE, DE NE SULI ne sacchara nation	FATE ate, amphetamine asp fate capsule, extende HUMAN PRESCRIPTION DRUG	d release Item C	Code (Source)	ND	
Marketing Category NDA DEXTROAMP 40N0HYDRX MPHETAMI extroamphetamir ulfate and amphe Product Inform Product Type Route of Administ	ATE, DE NE SULI ne sacchara stamine sul nation tration nt/Active	FATE ate, amphetamine asp fate capsule, extende HUMAN PRESCRIPTION DRUG ORAL Moiety	d release Item C	Code (Source) chedule	ND	E:70710-114
Marketing Category NIDA DEXTROAMP AONOHYDRJ MONHYDRJ MUPHETAMII extroamphetamir ulfate and amphe Product Inform Product Type Route of Adminis	ATE, DE NE SULI he sacchara itamine sul hation tration nt/Active Ingred	FATE ate, amphetamine asp fate capsule, extende prug oral Moiety lient Name	ltem C DEA S	Code (Source) chedule Basis of Str DEXTROAMPHETAM	ND CII rength	C:70710-118
Marketing Category NIDA DEXTROAMP MONOHYDRA MONOHYDRA MUPETAMII extroamphetamir ulfate and amphe Product Inform Product Type Route of Administ Cative Ingredie DEXTROAMPHETAMINE DEXTROAMPHETAMINE ASP.	ATE, DE NE SULI te saccharation tration tration nt/Active Ingred INE SACCHA E - UNILT247 ARTATE MOI	FATE ate, amphetamine asp fate capsule, extende HUMAN PRESCRIPTION DRUG ORAL Moiety lient Name wate (UNIK: G34155V073) U051F0;	ttem C DEA S	Code (Source) chedule Basis of Str DEXTROAMPHETAM SACCHARATE AMPHETAMINE ASP	Cil Cil rength IINE	C:70710-118
Category NNDA DEXTROAMP AONOHYDR/ MONOHYDR/ MONOHYDR/ MONOHYDR/ NOHYDR/ NOHYDR/ Product Type Route of Adminisi Active Ingredie EXTROAMPHETAMIN MEMPHETAMINE ASP DEXTROAMPHETAMIN	ATE, DE NE SULI te sacchara tration tration tration nt/Active ingred ine sacchare e - UNIE:247 artate MOI ck833KGX7E.	FATE tate, amphetamine asp fate capsule, extende DRUG ORAL Moiety lient Name WATE (UNII: 63415V073) VOITDMATE (UNII: 032PN VOITDMATE (UNII: 032PN	ttem C DEA S	Code (Source) chedule Basis of Str DEXTROAMPLETAM SACCHAMATE MONOMYDATE DEXTROAMPLETAM	rength INNE WARTATE	5trengt 6.25 mg
Marketing Category NIDA DEXTROAMP MONOHYDR/ MONOHYDR/ MONOHYDR/ MONOHYDR/ MONOHYDR/ Product Inform Product Inform Inform Product Inform	ATE, DE NE SULI te sacchar tamine sul nation tration tration tration nt/Active Ingred INE SACCHAE E - UNI:T247 ARTATE MOUCK933K0X7E INE SULFAT E - UNI:T247	FATE tate, amphetamine asp fate capsule, extende DRUG ORAL Moiety lient Name WATE (UNII: 63415V073) VOITDMATE (UNII: 032PN VOITDMATE (UNII: 032PN	d release Item C DEA S	Code (Source) chedule Basis of Str SACCHARATE AMPHETAMINE ASP MONOHYDARIA ASP	CII CII INNE ARTATE INNE	5:70710-118 <b>Strengt</b> 6.25 mg
Merketing Category NIDA DEXTROAMP MONOHYDRJ MONOHYDRJ MONOHYDRJ WIFLETAMII Varband Product Inform Product Inform Product Type Route of Administ Cative Ingredie CextroAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN DEXTROAMPHETAMIN	ATE, DE NE SULI te sacchar tamine sul nation tration tration tration nt/Active Ingred INE SACCHAE E - UNI:T247 ARTATE MOUCK933K0X7E INE SULFAT E - UNI:T247	FATE tate, amphetamine asp tate, amphetamine asp tate, asphetamine asp tate capsule, extended usuant PRESCRPTION DRUG ORA. Molety lient Name Name G83415V073) NOHYDRATE (UNI: 012PV ) (UNI: preso327N) USISTI	d release Item C DEA S	Code (Source) chedule Basis of Str SACHAPATE AMPHETAMINE ASP MONOHTODATE DEXTROJAPHETAM SULFATE	CII CII INNE ARTATE INNE	Strengt 6.25 mg 6.25 mg 6.25 mg

METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMAE (1.1) TYPE A (UNII: NX76LVST8)) POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532859)990)

	LC (UNII: 75EV7)		(20)				
	ANIUM DIOXID						
<b>n</b>	oduct Char						
			range) , WHITE (white)		Score		no score
	ape		range), with a (white)		Size		19mm
	vor				Imprint Code		1188;N
Co	ntains						
Pa	ckaging						
#	Item Code	Pa	ckage Description	Mari	eting Start Date	Mark	eting End Date
. 1	NDC:70710- 1188-1	100 in 1 BOT	LE; Type 0: Not a Combination	12/31/2			Date
•  :	1188-1	Product		12/31/2	010		
м	arketing	Informat	ion				
	Marketing		tion Number or Monogra	h Ma	rketing Start	Mar	keting End
	Category		Citation		Date	- nar	Date
ANE	AC	ANDA21008	0	12/30	/2016		
lex		nine sacchar	ate, amphetamine asparta fate capsule, extended rel		ydrate, dextroa	amphet	amine
Pr	oduct Info	mation					
Pre	oduct Type		HUMAN PRESCRIPTION	ltem Cod	e (Source)	N	DC:70710-11
Ro	ute of Admin	istration		DEA Sche	dule	c	1
RU	ate of Authin	istration	0.04L	DEA SCHE	uule	C.	
Ac	tive Ingred						
		Ingred	ient Name		Basis of Str		Streng
(DE	XTROAMPHETAM	IINE - UNII:TZ 47	RATE (UNII: G83415V073) U051FI)	s	EXTROAMPHETAMI ACCHARATE		7.5 mg
			NOHYDRATE (UNII: 01ZPV6200	4) A	MPHETAMINE ASP/ IONOHYDRATE		7.5 mg
DE	TROAMPHETA	MINE SULFAT	E (UNII: ]]7680327N)	4) A N	ONOHYDRATE EXTROAMPHETAM		7.5 mg
DE3 (DE	XTROAMPHETAN XTROAMPHETAN PHETAMINE SI	MINE SULFAT	E (UNII: ]]7680327N)	4) A N S	ONOHYDRATE	INE	-
DE DE	XTROAMPHETAN	MINE SULFAT	E (UNII: JJ7680327N) U051FI)	4) A N S	ONOHYDRATE EXTROAMPHETAMI ULFATE	INE	7.5 mg
DE3 (DE AM	XTROAMPHETA XTROAMPHETAM PHETAMINE SU I:CK833KGX7E)	MINE SULFAT IINE - UNII:TZ 47 JLFATE (UNII: 6	E (UNII: JJ7680327N) U051FI)	4) A N S	ONOHYDRATE EXTROAMPHETAMI ULFATE	INE	7.5 mg
DE3 (DE AM	XTROAMPHETAN XTROAMPHETAN PHETAMINE SI	MINE SULFAT IINE - UNII:TZ 47 JLFATE (UNII: 6	E (UNII: JJ7680327N) UOSIFI) DPV8NK46S) (AMPHETAMINE -	4) A N S	ONOHYDRATE EXTROAMPHETAMI ULFATE	INE	7.5 mg
	XTROAMPHETA XTROAMPHETAM PHETAMINE SU LCK833KGX7E) active Ingre	MINE SULFAT IINE - UNII:TZ47 JLFATE (UNII: 6 edients	E (UNII: JJ7680327N) UOSJFI) DPVBNK46S) (AMPHETAMINE - Ingredient Name	4) A N S	ONOHYDRATE EXTROAMPHETAMI ULFATE	INE	7.5 mg
DEX (DE AM UNI Ini FDI	XTROAMPHETA XTROAMPHETAM PHETAMINE SI ECK833KGX7E) ACTIVE Ingre &C BLUE NO. 2 DROXYPROPYL	MINE SULFAT INE - UNII:TZ47 JIFATE (UNII: 6 edients 2 (UNII: LO6KBR] CELLULOSE (	E (UNII: JJ7680327N) U051FI) DPVBNK465) (AMPHETAMINE - Ingredient Name DQK) E60000 WAMW) (UNII: RFW2)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
DE (DE (DE AM UNI Ini FDI HYI ME	XTROAMPHETA XTROAMPHETAM PHETAMINE SI E-CK833KGX7E) active Ingre &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC	MINE SULFAT INE - UNII:TZ47 JLFATE (UNII: 6 edients 2 (UNII: LOGKBR CELLULOSE ( ID-ETHYL ACF	E (UNII: )(7680327N) U051FI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) 1600000 WAMW) (UNII: RFW2) VLATE COPOLYMER (1:1) TY	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
DE (DE AM UNI In FDN HYI ME POI	XTROAMPHETA XTROAMPHETAM PHETAMINE SU PHETAMINE SU ECK833KGX7E) active Ingre &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LYVINYL ALCO	MINE SULFAT INE - UNI:T247 JLFATE (UNII: 6 edients 2 (UNII: LOGKBR: CELLULOSE ( ID-ETHYL ACF HOL, UNSPECI	E (UNI: JJ7680327N) UOSIFI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) 1600000 WAMW) (UNI: RFW2 VLATE COPOLYMER (1:1) YY FIED (UNI: 32595990)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
Ina FDI ME ST/	XTROAMPHETA XTROAMPHETAM PHETAMINE SU ICC6833KGX7E) active Ingro &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LYVINYL ALCO RACH, CORN (L CROSE (UNII: C	MINE SULFAT INE - UNII: T2 47 JLFATE (UNII: 6 edients 2 (UNII: LOGKBRT CELLULOSE ( ID-ETHYL ACF HOL, UNSPECI IDI: 08232NY35 151H8M554)	E (UNI: JJ7680327N) UOSIFI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) 1600000 WAMW) (UNI: RFW2 VLATE COPOLYMER (1:1) YY FIED (UNI: 32595990)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
	XTROAMPHETA XTROAMPHETAX PHETAMINE SI LCK833KGX7E) active Ingro &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LYVINYL ALCO ARCH, CORN (L CROSE (UNII: CFSV7)	MINE SULFAT INE - UNII: T2 47 JJFATE (UNII: 6 edients 2 (UNII: LO6K8R; CELLULOSE ( ID-ETHYL ACF HOL, UNSPECI INII: 08232NY33 ISJH8M554) 4RIU)	E (UNE: 19760327N) (UDSIT)) OPVENK46S) (AMPHETAMINE - Ingredient Name DOK) S00000 WAMW) (UNI: RFW22 VATE COPOLYMER (11.1) YY FED (UNI: 532859990) ()	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
	XTROAMPHETA XTROAMPHETAM PHETAMINE SU ICC6833KGX7E) active Ingro &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LYVINYL ALCO RACH, CORN (L CROSE (UNII: C	MINE SULFAT           INE - UNII: T2 47           JLFATE (UNII: 6           edients           2 (UNII: LO6KBR:           CELLULOSE (           ID-ETHYL ACF           HOL, UNSPECI           ID-ETHYL ACF           HOL, UNSPECI           IS151H8M554)           I4R1U)           # (UNII: 15FIX9)	E (UNE: [J7660327N) UOSITI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) G600000 WAMW) (UNI: RPV2I KATE COPOLYMER (11) TY FED (UNI: 532859990) (J)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
	XTROAMPHETA XTROAMPHETA XTROAMPHETAM PHETAMINE SI LCK833KGX7E) active Ingre &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LTVINYL ALCO ARCH, CORN (L CROSE (UNI: 7 C (UNI: 75EV7) ANIUM DIOXID	MINE SULFAT           INE - UNII: T2 47           JLFATE (UNII: 6           edients           2 (UNII: LO6KBR:           CELLULOSE (           ID-ETHYL ACF           HOL, UNSPECI           ID-ETHYL ACF           HOL, UNSPECI           IS151H8M554)           I4R1U)           # (UNII: 15FIX9)	E (UNE: [J7660327N) UOSITI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) G600000 WAMW) (UNI: RPV2I KATE COPOLYMER (11) TY FED (UNI: 532859990) (J)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
	KTROAMPHETA XTROAMPHETAMNES LCKB33KGXTEJ active Ingro &C BLUE NO. 2 DROXYPROPYL THACRYLC AC UVIVIYI ALCO ARCH, CORN (U CROSE (UNI: C CROSE (UNI: C C ROX (UNI: C C ROX (UNI: C C ROX (UNI: C C ROX (UNI: C ROX (	MINE SULFAT NINE - UNII: T2 47 JLFATE (UNII: 6 2dients 2 (UNII: LOGKBR: CELLULOSE ( ID-ETHYLACF HOL, UNSPECTIONI: 08232NY35 151HBMU) 4 (UNII: 15FIX9) E (UNII: 15FIX9) E (UNII: 82/960	E (UNE: [J7660327N) UOSITI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) G600000 WAMW) (UNI: RPV2I KATE COPOLYMER (11) TY FED (UNI: 532859990) (J)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULF	INE	7.5 mg
	XTROAMPHETA XTROAMPHETA XTROAMPHETAM PHETAMINE SI LCK833KGX7E) active Ingre &C BLUE NO. 2 DROXYPROPYL THACRYLIC AC LTVINYL ALCO ARCH, CORN (L CROSE (UNI: 7 C (UNI: 75EV7) ANIUM DIOXID	UNINE SULFAT ULFATE (UNII: 6 edients 2 (UNII: LOGKOR: 2 (UNII: LOGKOR: CELLUOSE ( ID-ETHYL ACF HOL, UNSPECT SIJHOM54) 4 (UNII: 1571X9 4 (UNII: 1571X9 4 (UNII: 2571X9 4 (UNII: 2571X9 4 (UNII: 2571X9) 4 (UNII: 2571X9	E (UNE, IPS60327N) UOSINI DPVBNK465) (AMPHETANINE - Ingredient Name DQK) G60000 WAMW) (UNI: RPV2I S20000 WAMW) (UNI: RPV2I S20000 WAMW) (DII: RPV2I (DII: S22859990) () 22P) CCBUM)	4) A S A ET671P)	IONOHYDRATE EXTROAMPHETAMI ULFATE MPHETAMINE SULI NX76LVST8j)	FATE	7.5 mg
DED DED DED DED DED DED DED DED	KTROAMPHETA KTROAMPHETA PHETAMINE STROAMPHETA ACTIVE ING ACTIVE ING ACTIVE NO. 2 BOXYPROPYL THACRYLIC AC DROXYPROPYL THACRYLIC AC CROSE (UNI: CC CROSE (UNI:	UNINE SULFAT ULFATE (UNII: 6 edients 2 (UNII: LOGKOR: 2 (UNII: LOGKOR: CELLUOSE ( ID-ETHYL ACF HOL, UNSPECT SIJHOM54) 4 (UNII: 1571X9 4 (UNII: 1571X9 4 (UNII: 2571X9 4 (UNII: 2571X9 4 (UNII: 2571X9) 4 (UNII: 2571X9	E (UNE: [J7660327N) UOSITI) DPVBNK465) (AMPHETAMINE - Ingredient Name DOK) G600000 WAMW) (UNI: RPV2I KATE COPOLYMER (11) TY FED (UNI: 532859990) (J)	4) A K	ONOHYDRATE EXTROLAMPIETAMI ULFATE MPHETAMINE SULJ NX76LVSTBJ) NX76LVSTBJ)	INE FATE	o score
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DEDE AM UNI UNI INI FDY ME POI ST/ ST/ ST/ ST/ ST/ ST/ ST/ ST/ ST/ ST/	KTROAMPHETA KTROAMPHETA KTROAMPHETA AKTROAMPHETA KROAMPHETA SC BLUE NO. 2 DROXYRROPT THACRYLIC AC UVIVIVITA ALCONN (U CROSE (UNI-C CONN (U CROSE (UNI-C CROSE	WINE SUFAT WINE SUFAT ULFATE (UNIE C CLUNIE CA CLUNIE LOCKBR CLUNIE LOCKBR	E (UNE: [P560327N) U0317I) DPVBNK465) (AMPHETAMINE - Ingredient Name DO(K) E000000 WANWY (UNE: RPVD) S000000 WANWY (UNE: RPVD) (UNE: S20509900) () 2001 ()	4) A A A A A A A A A A A A A A A A A A A	ONOHYDRATE EXTROLAMPIETAMI ULFATE MPHETAMINE SULJ NX76LVSTBJ) NX76LVSTBJ)	ne Fate	o score
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Zydus Pharmaceuticals (USA) Inc.