FOCALIN XR- dexmethylphenidate hydrochloride capsule, extended release
Sandoz Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FOCALIN XR safely and effectively. See full prescribing information for FOCALIN XR.

FOCALIN XR (dexmethylphenidate hydrochloride) extended-release capsules, for oral use, CII
Initial U.S. Approval: 2005

WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

Focalin XR has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including Focalin XR, can result in overdose and death (5.1, 9.2, 10).

- Before prescribing Focalin XR, assess each patient's risk for abuse, misuse, and addiction.
- Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug.
- Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

RECENT MAJOR CHANGES

Indications and Usage (1) 09/2025
Warnings and Precautions (5.7) 09/2025

INDICATIONS AND USAGE

Focalin XR is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (1).

Limitations of Use

The use of Focalin XR is not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage (5.7, 8.4).

DOSAGE AND ADMINISTRATION

- Patients new to methylphenidate: Recommended starting dose is 5 mg once daily for pediatric patients and 10 mg once daily for adults with or without food in the morning (2.2).
- Patients currently on methylphenidate: Focalin XR dosage is half (1/2) the current total daily dosage of methylphenidate (2.2).
- Patients currently on Focalin (dexmethylphenidate) immediate-release tablets: Give the same daily dose of Focalin XR (2.2).
- Titrate weekly in increments of 5 mg in pediatric patients and 10 mg in adult patients (2.2).
- Maximum recommended daily dose: 30 mg in pediatric patients and 40 mg in adults (2.2).
- Capsules may be swallowed whole or opened and the entire contents sprinkled on applesauce (2.3).

DOSAGE FORMS AND STRENGTHS

Extended-release capsules: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg of dexmethylphenidate hydrochloride (3).

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of Focalin XR (4).
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days (4).

WARNINGS AND PRECAUTIONS

- *Risks to Patients with Serious Cardiac Disease:* Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious

cardiac disease (5.2).
- *Increased Blood Pressure and Heart Rate:* Monitor blood pressure and pulse (5.3).
- *Psychiatric Adverse Reactions:* Prior to initiating Focalin XR, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing Focalin XR (5.4).
- *Priapism:* If abnormally sustained or frequent and painful erections occur, patients should seek immediate medical attention (5.5).
- *Peripheral Vasculopathy, including Raynaud's Phenomenon:* Careful observation for digital changes is necessary during Focalin XR treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5.6).
- *Long-Term Suppression of Growth in Pediatric Patients:* Closely monitor growth (height and weight) in pediatric patients. Pediatric patients not growing or gaining height or weight as expected may need to have their treatment interrupted (5.7).
- *Acute Angle Closure Glaucoma:* Focalin XR-treated patients considered at risk for acute angle closure glaucoma (e.g., patients with significant hyperopia) should be evaluated by an ophthalmologist (5.8).
- *Increased Intraocular Pressure (IOP) and Glaucoma:* Prescribe Focalin XR to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor patients with a history of increased IOP or open angle glaucoma (5.9).
- *Motor and Verbal Tics, and Worsening of Tourette's Syndrome:* Before initiating Focalin XR, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome. Discontinue treatment if clinically appropriate (5.10).

ADVERSE REACTIONS

The most common adverse reactions (greater than or equal to 5% and twice the rate of placebo):

- Pediatric patients 6 to 17 years: dyspepsia, decreased appetite, headache, and anxiety (6.1).
- Adults: dry mouth, dyspepsia, headache, pharyngolaryngeal pain, and anxiety (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc., at 1-800-525-8747, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- *Antihypertensive Drugs:* Monitor blood pressure. Adjust dosage of antihypertensive drug as needed (7.1).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 9/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

Focalin XR has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including Focalin XR, can result in overdose and death *[see Overdosage (10)],* and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing Focalin XR, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout Focalin XR treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction *[see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2)].*

1 INDICATIONS AND USAGE

Focalin XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) *[see Clinical Studies (14)]*.

Limitations of Use

The use of Focalin XR is not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage *[see Warnings and Precautions (5.7), Use in Specific Populations (8.4)].*

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating patients with Focalin XR, assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam) *[see Warnings and Precautions (5.2)]*.
- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome before initiating Focalin XR *[see Warnings and Precautions (5.10)]*.

2.2 Recommended Dosage

Patients New to Methylphenidate

The recommended starting dosage of Focalin XR for patients who are not currently taking dexmethylphenidate or racemic methylphenidate, or for patients who are on stimulants other than methylphenidate are:

- Pediatric patients: Start with 5 mg orally once daily in the morning with or without

food.
- Adult patients: Start with 10 mg orally once daily in the morning with or without food.

Patients Currently on Methylphenidate

The recommended starting dose of Focalin XR for patients currently using methylphenidate is half (1/2) the total daily dose of racemic methylphenidate.

Patients currently using Focalin (dexmethylphenidate) immediate-release tablets may be given the same daily dose of Focalin XR.

Titration Schedule

The dose may be titrated weekly in increments of 5 mg in pediatric patients and 10 mg in adult patients. The dose should be individualized according to the needs and response of the patient. Daily doses above 30 mg in pediatrics and 40 mg in adults have not been studied and are not recommended.

2.3 Administration Instructions

Focalin XR is administered orally and may be taken whole or the capsule may be opened and the entire contents sprinkled onto applesauce. If the patient is using the sprinkled 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.

2.4 Dosage Reduction and Discontinuation

If paradoxical aggravation of symptoms or other adverse reactions occur, reduce the dosage, or if necessary, discontinue Focalin XR. If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

3 DOSAGE FORMS AND STRENGTHS

- 5 mg extended-release capsules – light blue opaque cap and body (imprinted with “SDZ” on cap and “D5” on the body)
- 10 mg extended-release capsules – light caramel opaque cap and body (imprinted with “SDZ” on cap and “D10” on the body)
- 15 mg extended-release capsules – green opaque cap and body (imprinted with “SDZ” on cap and “D15” on the body)
- 20 mg extended-release capsules – white opaque cap and body (imprinted with “SDZ” on cap and “D20” on the body)
- 25 mg extended-release capsules – light blue opaque cap and white opaque body (imprinted with “SDZ” on cap and “D25” on the body)
- 30 mg extended-release capsules – light caramel opaque cap and white opaque body (imprinted with “SDZ” on cap and “D30” on the body)
- 35 mg extended-release capsules – light blue opaque cap and light caramel opaque body (imprinted with “SDZ” on cap and “D35” on the body)

- 40 mg extended-release capsules – green opaque cap and white opaque body (imprinted with “SDZ” on cap and “D40” on the body)

4 CONTRAINDICATIONS

- Hypersensitivity to methylphenidate or other components of Focalin XR. Hypersensitivity reactions, such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate *[see Adverse Reactions (6.1)]*.
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs) or within 14 days following discontinuation of treatment with an MAOI, because of the risk of hypertensive crises *[see Drug Interactions (7.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Focalin XR has a high potential for abuse and misuse. The use of Focalin XR exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Focalin XR can be diverted for non-medical use into illicit channels or distribution *[see Drug Abuse and Dependence (9.2)].* Misuse and abuse of CNS stimulants, including Focalin XR, can result in overdose and death *[see Overdosage (10)]*, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing Focalin XR, assess each patient’s risk for abuse, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store Focalin XR in a safe place, preferably locked, and instruct patients to not give Focalin XR to anyone else. Throughout Focalin XR treatment, reassess each patient’s risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

5.2 Risks to Patients with Serious Cardiac Disease

Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage.

Avoid Focalin XR use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

5.3 Increased Blood Pressure and Heart Rate

CNS stimulants cause an increase in blood pressure (mean increase approximately 2 to 4 mmHg) and heart rate (mean increase approximately 3 to 6 beats per minute). Some patients may have larger increases.

Monitor all Focalin XR-treated patients for hypertension and tachycardia.

5.4 Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis

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

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed mood episode in patients. Prior to initiating Focalin XR treatment, screen patients for risk factors for developing manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms

CNS stimulants, at the recommended dosage, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared to 0% of placebo-treated patients. If such symptoms occur, consider discontinuing Focalin XR.

5.5 Priapism

Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate use in both adult and pediatric male patients. Although priapism was not reported with methylphenidate initiation, it developed after some time on methylphenidate, often subsequent to an increase in dosage. Priapism also occurred during methylphenidate withdrawal (drug holidays or during discontinuation).

Focalin XR-treated patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

5.6 Peripheral Vasculopathy, Including Raynaud's Phenomenon

CNS stimulants, including Focalin XR, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, sequelae have included digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at and at the therapeutic dosage of CNS stimulants in all age groups throughout the course of treatment. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant.

Careful observation for digital changes is necessary during Focalin XR treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for Focalin XR-treated patients who develop signs or symptoms of peripheral vasculopathy.

5.7 Long-Term Suppression of Growth in Pediatric Patients

Focalin XR is not approved for use and is not recommended in pediatric patients below 6 years of age *[see Use in Specific Populations (8.4)].*

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients.

In a 7-week, double-blind, placebo-controlled study of Focalin XR, the mean weight gain

was greater for pediatric patients (ages 6 to 17 years) receiving placebo (+ 0.4 kg) than for patients receiving Focalin XR (- 0.5 kg).

Careful follow-up of weight and height in pediatric patients 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 patients over 36 months (to the ages of 10 to 13 years), suggests that pediatric patients who received methylphenidate for 7 days per week throughout the year had a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this development period.

Closely monitor growth (weight and height) in Focalin XR-treated pediatric patients. Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

5.8 Acute Angle Closure Glaucoma

There have been reports of angle closure glaucoma associated with methylphenidate treatment. Although the mechanism is not clear, Focalin XR-treated patients considered at risk for acute angle closure glaucoma (e.g., patients with significant hyperopia) should be evaluated by an ophthalmologist.

5.9 Increased Intraocular Pressure and Glaucoma

There have been reports of an elevation of intraocular pressure (IOP) associated with methylphenidate treatment *[see Adverse Reactions (6.2)].*

Prescribe Focalin to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor Focalin XR-treated patients with a history of abnormally increased IOP or open angle glaucoma.

5.10 Motor and Verbal Tics, and Worsening of Tourette's Syndrome

CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported *[see Adverse Reactions (6.2)].*

Before initiating Focalin XR, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor Focalin -treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

6 ADVERSE REACTIONS

The following are discussed in more detail in other sections of the labeling:

- Abuse, Misuse, and Addiction *[see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)]*
- Known hypersensitivity to methylphenidate or other ingredients of Focalin XR *[see Contraindications (4)]*
- Hypertensive Crisis with Concomitant Use of Monoamine Oxidase Inhibitors *[see Contraindications (4), Drug Interactions (7.1)]*

- Risks to Patients with Serious Cardiac Disease *[see Warnings and Precautions (5.2)]*
- Increased Blood Pressure and Heart Rate *[see Warnings and Precautions (5.3)]*
- Psychiatric Adverse Reactions *[see Warnings and Precautions (5.4)]*
- Priapism *[see Warnings and Precautions (5.5)]*
- Peripheral Vasculopathy, Including Raynaud's Phenomenon *[see Warnings and Precautions (5.6)]*
- Long-Term Suppression of Growth in Pediatric Patients *[see Warnings and Precautions (5.7)]*
- Acute Angle Closure Glaucoma *[see Warnings and Precautions (5.8)]*
- Increased Intraocular Pressure and Glaucoma *[see Warnings and Precautions (5.9)]*
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome *[see Warnings and Precautions (5.10)]*

6.1 Clinical Trials Experience

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.

Adverse Reactions in Studies with Focalin XR in Pediatric Patients with ADHD

The safety data in this section is based on data from a 7-week controlled clinical study of Focalin XR in 100 (103 randomized) pediatric patients with ADHD ages 6 to 17 years (ages 6 to 12, n = 86; ages 13 to 17, n = 17).

This study was a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the time of onset, duration of efficacy, tolerability, safety of Focalin XR 5 mg to 30 mg/day who met The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for ADHD *[see Clinical Studies (14.1)]*.

Most Common Adverse Reactions (incidence of greater than or equal to 5% and at least twice placebo): dyspepsia, decreased appetite, headache, and anxiety.

Adverse Reactions Leading to Discontinuation: 50 of 684 (7.3%) pediatric patients treated with Focalin (dexmethylphenidate) immediate-release tablets experienced an adverse reaction that resulted in discontinuation. The most common reasons for discontinuation were twitching (described as motor or vocal tics), anorexia, insomnia, and tachycardia (approximately 1% each).

Table 1 enumerates adverse reactions for the placebo-controlled, parallel-group study in children and adolescents with ADHD at flexible Focalin XR doses of 5–30 mg/day. The table includes only those events that occurred in 5% or more of patients treated with Focalin XR and for which the incidence in patients treated with Focalin XR was at least twice the incidence in placebo-treated patients.

Table 1: Common Adverse Reactions in Pediatric Patients (6 to 17 years of age) With ADHD

System organ class **Adverse reaction**	**Focalin XR** **N = 53**	**Placebo** **N = 47**
Gastrointestinal disorders	38%	19%
Dyspepsia	8%	4%
Metabolism and nutrition disorders	34%	11%

Decreased appetite	30%	9%
Nervous system disorders	30%	13%
Headache	25%	11%
Psychiatric disorders	26%	15%
Anxiety	6%	0%

Abbreviation: ADHD, attention deficit hyperactivity disorder.

Table 2 below enumerates the incidence of dose-related adverse reactions that occurred during a fixed-dose, double-blind, placebo-controlled trial in pediatric patients with ADHD taking Focalin XR up to 30 mg daily versus placebo. The table includes only those reactions that occurred in patients treated with Focalin XR for which the incidence was at least 5% and greater than the incidence among placebo-treated patients.

Table 2: Dose-Related Adverse Reactions in Pediatric Patients (6 to 17 years of age) With ADHD

System organ class **Adverse reaction**	**Focalin XR 10 mg/day** **N = 64**	**Focalin XR 20 mg/day** **N = 60**	**Focalin XR 30 mg/day** **N = 58**	**Placebo** **N = 63**
Gastrointestinal disorders	22%	23%	29%	24%
Vomiting	2%	8%	9%	0%
Metabolism and nutritional disorders	16%	17%	22%	5%
Anorexia	5%	5%	7%	0
Psychiatric disorders	19%	20%	38%	8%
Insomnia	5%	8%	17%	3%
Depression	0	0	3%	0
Mood swings	0%	0%	3%	2%
Other adverse reactions				
Irritability	0%	2%	5%	0%
Nasal congestion	0%	0%	5%	0%
Pruritus	0%	0%	3%	0%

Abbreviation: ADHD, attention deficit hyperactivity disorder.

Adverse Reactions in Studies with Focalin XR in Adult Patients with ADHD

The safety data in this section is based on data from a 5-week controlled clinical study of Focalin XR in 218 adult patients (221 randomized) with ADHD ages 18 to 60 years. In this study, 101 adult patients were treated for at least 6 months.

This study was a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy, safety, and tolerability of Focalin XR 20 mg, 30 mg, or 40 mg daily who met DSM-IV criteria for ADHD *[see Clinical Studies (14.2)]*.

Most Common Adverse Reactions (incidence of greater than or equal to 5% and at least twice placebo): dry mouth, dyspepsia, headache, anxiety, and pharyngolaryngeal pain.

Adverse Reactions Leading to Discontinuation: During the double-blind phase of the study, 10.7% of the Focalin XR-treated patients and 7.5% of the placebo-treated

patients discontinued due to adverse reactions. Three patients (1.8%) in the Focalin XR discontinued due to insomnia and jittery respectively; and two patients (1.2%) in the Focalin XR discontinued due to anorexia and anxiety, respectively.

Table 3 enumerates adverse reactions for the placebo-controlled, parallel-group study in adults with ADHD at fixed Focalin XR doses of 20, 30, or 40 mg/day. The table includes only those events that occurred in 5% or more of patients in a Focalin XR dose group and for which the incidences in patients treated with Focalin XR appeared to increase with dose.

Table 3: Dose-Related Adverse Reactions in Adult Patients (18 to 60 years of age) With ADHD

System organ class Adverse reaction	Focalin XR 20 mg N = 57	Focalin XR 30 mg N = 54	Focalin XR 40 mg N = 54	Placebo N = 53
Gastrointestinal disorders	28%	32%	44%	19%
Dry mouth	7%	20%	20%	4%
Dyspepsia	5%	9%	9%	2%
Nervous system disorders	37%	39%	50%	28%
Headache	26%	30%	39%	19%
Psychiatric disorders	40%	43%	46%	30%
Anxiety	5%	11%	11%	2%
Respiratory, thoracic, and mediastinal disorders	16%	9%	15%	8%
Pharyngolaryngeal pain	4%	4%	7%	2%

Two other adverse reactions occurring in clinical trials with Focalin XR at a frequency greater than placebo, but which were not dose related were: feeling jittery (12% and 2%, respectively) and dizziness (6% and 2%, respectively).

Table 4 summarizes changes in vital signs and weight that were recorded in the adult study (N = 218) of Focalin XR in the treatment of ADHD.

Table 4: Changes (Mean ± SD) in Vital Signs and Weight by Randomized Dose During Double-Blind Treatment–Adults

	Focalin XR 20 mg (N = 57)	Focalin XR 30 mg (N = 54)	Focalin XR 40 mg (N = 54)	Placebo (N = 53)
Pulse (bpm)	3.1 ± 11.1	4.3 ± 11.7	6 ± 10.1	-1.4 ± 9.3
Diastolic BP (mmHg)	-0.2 ± 8.2	1.2 ± 8.9	2.1 ± 8	0.3 ± 7.8
Weight (kg)	-1.4 ± 2	-1.2 ± 1.9	-1.7 ± 2.3	-0.1 ± 3.9

6.2 Postmarketing Experience

The following additional adverse reactions have been identified during postapproval use of dexmethylphenidate. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency

or establish a causal relationship to drug exposure.

Musculoskeletal: rhabdomyolysis

Immune System Disorders: hypersensitivity reactions, including angioedema and anaphylaxis

Adverse Reactions Reported With All Ritalin and Focalin Formulations

The following adverse reactions associated with the use of all Ritalin and Focalin formulations were identified in clinical trials, spontaneous reports, and literature. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

Infections and Infestations: nasopharyngitis

Blood and the Lymphatic System Disorders: leukopenia, thrombocytopenia, anemia

Immune System Disorders: hypersensitivity reactions, including angioedema and anaphylaxis

Metabolism and Nutrition Disorders: decreased appetite, reduced weight gain, and suppression of growth during prolonged use in pediatric patients

Psychiatric Disorders: insomnia, anxiety, restlessness, agitation, psychosis (sometimes with visual and tactile hallucinations), depressed mood, depression

Nervous System Disorders: headache, dizziness, tremor, dyskinesia, including choreoathetoid movements, drowsiness, convulsions, cerebrovascular disorders (including vasculitis, cerebral hemorrhages and cerebrovascular accidents), serotonin syndrome in combination with serotonergic drugs

Eye Disorders: blurred vision, difficulties in visual accommodation

Cardiac Disorders: tachycardia, palpitations, increased blood pressure, arrhythmias, angina pectoris

Respiratory, Thoracic, and Mediastinal Disorders: cough

Gastrointestinal Disorders: dry mouth, nausea, vomiting, abdominal pain, dyspepsia

Hepatobiliary Disorders: abnormal liver function, ranging from transaminase elevation to severe hepatic injury

Skin and Subcutaneous Tissue Disorders: hyperhidrosis, pruritus, urticaria, exfoliative dermatitis, scalp hair loss, erythema multiforme rash, thrombocytopenic purpura

Musculoskeletal and Connective Tissue Disorders: arthralgia, muscle cramps, rhabdomyolysis, trismus

Investigations: weight loss (adult ADHD patients)

Vascular Disorders: peripheral coldness, Raynaud's phenomenon

Additional Adverse Reactions Reported with Other Methylphenidate Products

The list below shows adverse reactions not listed with Ritalin and Focalin formulations that have been reported with other methylphenidate products based on clinical trials data and post-marketing spontaneous reports.

Blood and Lymphatic Disorders: pancytopenia

Immune System Disorders: hypersensitivity reactions, such as auricular swelling, bullous conditions, eruptions, exanthemas

Psychiatric Disorders: affect lability, mania, disorientation, libido changes

Nervous System Disorders: migraine, motor and verbal tics

Eye Disorders: diplopia, increased intraocular pressure, mydriasis

Cardiac Disorders: sudden cardiac death, myocardial infarction, bradycardia, extrasystole, supraventricular tachycardia, ventricular extrasystole

Respiratory, Thoracic, and Mediastinal Disorders: pharyngolaryngeal pain, dyspnea

Gastrointestinal Disorders: diarrhea, constipation

Skin and Subcutaneous Tissue Disorders: angioneurotic edema, erythema, fixed drug eruption

Musculoskeletal, Connective Tissue, and Bone Disorders: myalgia, muscle twitching

Renal and Urinary Disorders: hematuria

Reproductive System and Breast Disorders: gynecomastia

General Disorders: fatigue, hyperpyrexia

Urogenital Disorders: priapism

7 DRUG INTERACTIONS

7.1 Clinically Important Drug Interactions With Focalin XR

Table 5 presents clinically important drug interactions with Focalin XR.

Table 5: Clinically Important Drug Interactions With Focalin XR

Monoamine Oxidase Inhibitors (MAOIs)	
Clinical Impact	Concomitant use of MAOIs and CNS stimulants, including Focalin XR, can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure *[see Contraindications (4)].*
Intervention	Concomitant use of Focalin XR with MAOIs or within 14 days after discontinuing MAOI treatment is contraindicated.
Antihypertensive Drugs	
Clinical impact	Focalin XR may decrease the effectiveness of drugs used to treat hypertension *[see Warnings and Precautions (5.3)].*
Intervention	Monitor blood pressure and adjust the dosage of the antihypertensive drug as

	needed.
Halogenated Anesthetics	
Clinical impact	Concomitant use of halogenated anesthetics and Focalin XR may increase the risk of sudden blood pressure and heart rate increase during surgery.
Intervention	Avoid use of Focalin XR in patients being treated with anesthetics on the day of surgery.
Risperidone	
Clinical impact	Combined use of methylphenidate with risperidone when there is a change, whether an increase or decrease, in dosage of either or both medications, may increase the risk of extrapyramidal symptoms (EPS)
Intervention	Monitor for signs of EPS

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 ADHD medications, including Focalin XR, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for ADHD medications at 1-866-961-2388 or visiting https://womensmentalhealth.org/adhd-medications/.

Risk Summary

Dexmethylphenidate is the *d-threo* enantiomer of racemic methylphenidate. Published studies and postmarketing reports on methylphenidate use during pregnancy have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. There may be risks to the fetus associated with the use of CNS stimulants during pregnancy *(see Clinical Considerations)*. Embryo-fetal development studies in rats showed delayed fetal skeletal ossification at doses up to 5 times the maximum recommended human dose (MRHD) of 20 mg/day given to adults based on plasma levels. A decrease in pup weight in males was observed in a pre- and post-natal development study with oral administration of methylphenidate to rats throughout pregnancy and lactation at doses 5 times the MRHD of 20 mg/day given to adults based on plasma levels *(see 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, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

CNS stimulants, such as Focalin XR, can cause vasoconstriction and thereby decrease placental perfusion. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy; however, premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers.

Data

Animal Data

In embryo-fetal development studies conducted in rats and rabbits, dexmethylphenidate was administered orally at doses of up to 20 and 100 mg/kg/day, respectively, during the period of organogenesis. No evidence of malformations was found in either the rat or rabbit study; however, delayed fetal skeletal ossification was observed at the highest dose level in rats. When dexmethylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 20 mg/kg/day, post-weaning body weight gain was decreased in male offspring at the highest dose, but no other effects on postnatal development were observed. At the highest doses tested, plasma levels [area under the curves (AUCs)] of dexmethylphenidate in pregnant rats and rabbits were approximately 5 and 1 times, respectively, those in adults dosed with 20 mg/day. Plasma levels in adults were comparatively similar to plasma levels in adolescents.

Racemic methylphenidate has been shown to cause malformations (increased incidence of fetal spina bifida) in rabbits when given in doses of 200 mg/kg/day throughout organogenesis.

8.2 Lactation

Risk Summary

Dexmethylphenidate is the *d-threo* enantiomer of racemic methylphenidate. Limited published literature, based on milk sampling from seven mothers' reports that methylphenidate is present in human milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of adverse effects on the breastfed infant and no effects on milk production. Long-term neurodevelopmental effects on infants from stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Focalin XR and any potential adverse effects on the breastfed infant from Focalin XR or from the underlying maternal condition.

Clinical Considerations

Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

8.4 Pediatric Use

The safety and effectiveness of Focalin XR have not been established in pediatric patients below the age of 6 years.

In studies evaluating extended-release methylphenidate products, patients 4 to <6 years of age had higher systemic methylphenidate exposures than those observed in older pediatric patients at the same dosage. Pediatric patients 4 to <6 years of age also had a higher incidence of adverse reactions, including weight loss.

The safety and effectiveness of Focalin XR for the treatment of ADHD have been established in pediatric patients aged 6 to 17 years in two adequate and well-controlled clinical trials [see Clinical Studies (14.2)].

Long Term Suppression of Growth

Growth should be monitored during treatment with stimulants, including Focalin XR. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted *[see Warnings and Precautions (5.7)]*.

Juvenile Animal Toxicity Data

Rats treated with racemic methylphenidate early in the postnatal period through sexual maturation demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females only. The doses at which these findings were observed are at least 6 times the MRHD of 60 mg/day given to children on a mg/m^2 basis.

In a study conducted in young rats, racemic methylphenidate was administered orally at doses of up to 100 mg/kg/day for 9 weeks, starting early in the postnatal period (postnatal Day 7) and continuing through sexual maturity (postnatal Week 10). When these animals were tested as adults (postnatal Weeks 13 to 14), decreased spontaneous locomotor activity was observed in males and females previously treated with 50 mg/kg/day (approximately 4 times the MRHD of 60 mg/day of racemic methylphenidate given to children on a mg/m^2 basis) or greater, and a deficit in the acquisition of a specific learning task was seen in females exposed to the highest dose (8 times the MRHD given to children on a mg/m^2 basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (approximately 0.5 times the MRHD given to children on a mg/m^2 basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.

8.5 Geriatric Use

Focalin XR has not been studied in the geriatric population.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Focalin XR contains dexmethylphenidate hydrochloride, a Schedule II controlled substance.

9.2 Abuse

Focalin XR has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction *[see Warnings and Precautions (5.1)]*. Focalin XR can be diverted for non-medical use into illicit channels or distribution.

Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the

drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence.

Misuse and abuse of methylphenidate may cause increased heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including Focalin XR, can result in overdose and death *[see Overdosage (10)]*, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

9.3 Dependence

Physical Dependence

Focalin XR may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Withdrawal signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including Focalin XR include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Focalin XR may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

10 OVERDOSAGE

Clinical Effects of Overdose

Overdose of CNS stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

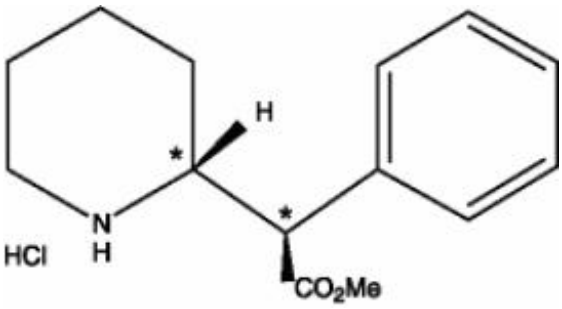
Overdose Management

Consider the possibility of multiple drug ingestion. The pharmacokinetic profile of Focalin XR should be considered when treating patients with overdose. Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

Focalin XR contains dexmethylphenidate hydrochloride, a CNS stimulant. Dexmethylphenidate hydrochloride is the *d-threo* enantiomer of racemic methylphenidate hydrochloride. Focalin XR is an extended-release formulation of dexmethylphenidate with a bi-modal release profile. Each bead-filled Focalin XR capsule contains half the dose as immediate-release beads and half as enteric-coated, delayed-release beads, thus providing an immediate release of dexmethylphenidate and a delayed release of dexmethylphenidate. Focalin XR is intended for oral administration and is available as 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg extended-release capsules.

Chemically, dexmethylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride, (R,R')-(+)-. Its molecular formula is $C_{14}H_{19}NO_2$•HCl. Its structural formula is:



Note* = asymmetric carbon center

Dexmethylphenidate hydrochloride is a white to off-white powder. Its solutions are acid to litmus. It is freely soluble in water and in methanol, soluble in alcohol, and slightly soluble in chloroform and in acetone. Its molecular weight is 269.77 g/mol.

Inactive ingredients: ammonio methacrylate copolymer, gelatin, methacrylic acid copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide, and triethyl citrate.

Each strength capsule also contains colorant ingredients in the capsule shell as follows:

- 5 mg: E132 FD&C Blue No. 2
- 10 mg: FDA/E172 iron oxide yellow
- 15 mg: FD&C Blue No. 2, FDA/E172 iron oxide yellow
- 20 mg: contains no colorants
- 25 mg: E132 FD&C Blue No. 2
- 30 mg: FDA/E172 iron oxide yellow
- 35 mg: E132 FD&C Blue No. 2, FDA/E172 iron oxide yellow
- 40 mg: E132 FD&C Blue No. 2, FDA/E172 iron oxide yellow

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dexmethylphenidate hydrochloride is a CNS stimulant. The mode of therapeutic action in ADHD is not known.

12.2 Pharmacodynamics

Dexmethylphenidate is the more pharmacologically active *d*-enantiomer of racemic methylphenidate. Methylphenidate blocks the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Cardiac Electrophysiology

At the recommended maximum total daily dosage of 40 mg, Focalin XR does not prolong the QTc interval to any clinically relevant extent.

12.3 Pharmacokinetics

Absorption

Focalin XR produces a bi-modal plasma concentration-time profile (i.e., 2 distinct peaks approximately 4 hours apart) when orally administered to healthy adults. The initial rate of absorption for Focalin XR is similar to that of Focalin tablets as shown by the similar rate parameters between the 2 formulations, i.e., first peak concentration (C_{max1}), and time to the first peak (t_{max1}), which is reached in 1.5 hours (typical range 1 to 4 hours). The mean time to the interpeak minimum (t_{minip}) is slightly shorter, and time to the second peak (t_{max2}) is slightly longer for Focalin XR given once daily (about 6.5 hours; range, 4.5 to 7 hours) compared to Focalin tablets given in 2 doses 4 hours apart (see Figure 1), although the ranges observed are greater for Focalin XR.

Focalin XR given once daily exhibits a lower second peak concentration (C_{max2}), higher interpeak minimum concentrations (C_{minip}), and fewer peak and trough fluctuations than Focalin tablets given in 2 doses given 4 hours apart. This is due to an earlier onset and more prolonged absorption from the delayed-release beads (see Figure 1).

The ratio of geometric mean of $AUC_{(0\text{-}inf)}$ and C_{max} after administration of Focalin XR given once daily are 1.02 and 0.86 respectively, to the same total dose of Focalin tablets given in 2 doses 4 hours apart. The variability in C_{max}, C_{min}, and AUC is similar between Focalin XR and Focalin immediate-release tablets with approximately a 3-fold range in each.

Approximately 90% of the dose is absorbed after oral administration of radiolabeled racemic methylphenidate. However, due to first pass metabolism the mean absolute bioavailability of dexmethylphenidate when administered in various formulations was 22% to 25%.

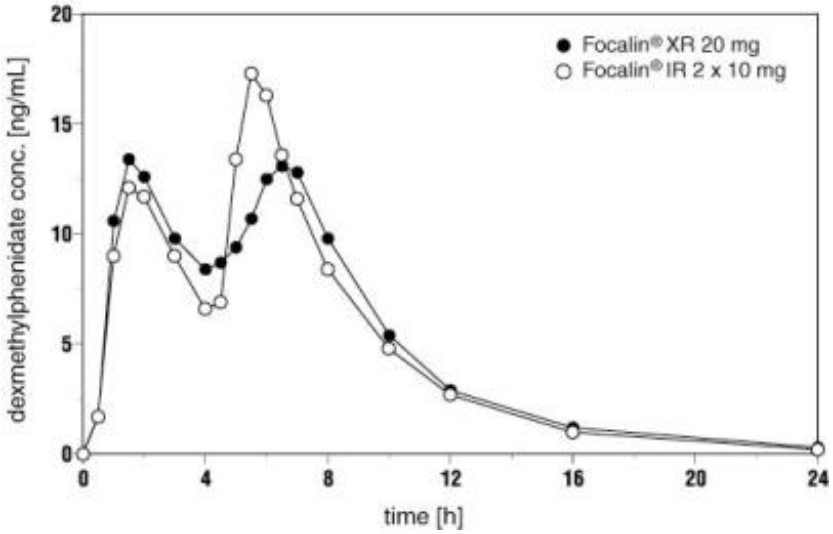


Figure 1. Mean Dexmethylphenidate Plasma Concentration-Time Profiles After Administration 1 x 20 mg Focalin XR (n = 24) Capsules and 2 x 10 mg Focalin Immediate-Release Tablets (n = 25)

After single dose administration, Focalin XR demonstrated dose proportional pharmacokinetics (PK) in the range of 5 mg to 40 mg.

For patients unable to swallow the capsule, the contents may be sprinkled on applesauce and administered *[see Dosage and Administration (2)]*.

Distribution

The plasma protein binding of dexmethylphenidate is not known; racemic methylphenidate is bound to plasma proteins by 12% to 15%, independent of concentration. Dexmethylphenidate shows a volume of distribution of 2.65 ± 1.11 L/kg.

Elimination

Plasma dexmethylphenidate concentrations decline monophasically following oral administration of Focalin XR. The mean terminal elimination half-life of dexmethylphenidate was about 3 hours in healthy adults. Pediatric patients tend to have slightly shorter half-lives with means of 2 to 3 hours. Dexmethylphenidate was eliminated with a mean clearance of 0.40 ± 0.12 L/hr/kg after intravenous administration.

Metabolism

In humans, dexmethylphenidate is metabolized primarily via de-esterification to *d*-α-phenyl-piperidine acetic acid (also known as *d*-ritalinic acid). This metabolite has little or no pharmacological activity. There is no *in vivo* interconversion to the *l-threo*-enantiomer.

Excretion

After oral dosing of radiolabeled racemic methylphenidate in humans, about 90% of the radioactivity was recovered in urine. The main urinary metabolite of racemic *dl*-methylphenidate was *dl*-ritalinic acid, accountable for approximately 80% of the dose. Urinary excretion of parent compound accounted for 0.5% of an intravenous dose.

Studies in Specific Populations

Male and Female Patients

After administration of Focalin XR, the first peak, (C_{max1}) was on average 45% higher in women. The interpeak minimum and the second peak also tended to be slightly higher in women although the difference was not statistically significant, and these patterns remained even after weight normalization.

Racial or Ethnic Groups

There is insufficient experience with the use of Focalin XR to detect ethnic variations in pharmacokinetics.

Pediatric Patients

The pharmacokinetics of dexmethylphenidate after Focalin XR administration have not been studied in pediatrics less than 18 years of age. When a similar formulation of racemic methylphenidate was examined in 15 patients between 10 and 12 years of age, and 3 patients with ADHD between 7 and 9 years of age, the time to the first peak was similar, although the time until the between peak minimum, and the time until the second peak were delayed and more variable in pediatric patients compared to adults. After administration of the same dose to pediatric patients and adults, concentrations in pediatric patients were approximately twice the concentrations observed in adults. This higher exposure is almost completely due to smaller body size as no relevant age-related differences in dexmethylphenidate pharmacokinetic parameters (i.e., clearance and volume of distribution) are observed after normalization to dose and weight.

Patients with Renal Impairment

There is no experience with the use of Focalin XR in patients with renal impairment. Since renal clearance is not an important route of methylphenidate elimination, renal impairment is expected to have little effect on the pharmacokinetics of Focalin XR.

Patients with Hepatic Impairment

There is no experience with the use of Focalin XR in patients with hepatic impairment.

Drug Interaction Studies

Methylphenidate is not metabolized by cytochrome P450 (CYP) isoenzymes to a clinically relevant extent. Inducers or inhibitors of CYPs are not expected to have any relevant impact on methylphenidate pharmacokinetics. Conversely, the *d*- and *l*-enantiomers of methylphenidate did not relevantly inhibit CYP1A2, 2C8, 2C9, 2C19, 2D6, 2E1, or 3A. Clinically, methylphenidate coadministration did not increase plasma concentrations of the CYP2D6 substrate desipramine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenesis

Lifetime carcinogenicity studies have not been carried out with dexmethylphenidate. In a lifetime carcinogenicity study carried out in B6C3F1 mice, racemic methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in

hepatoblastomas was seen at a daily dose of approximately 60 mg/kg/day. This dose is approximately 2 times the MRHD of 60 mg/day of racemic methylphenidate given to children on a mg/m^2 basis. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Racemic methylphenidate did not cause any increase in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 4 times the MRHD (children) of 60 mg/day of racemic methylphenidate in children on a mg/m^2 basis.

In a 24-week carcinogenicity study with racemic methylphenidate in the transgenic mouse strain p53+/-, which is sensitive to genotoxic carcinogens, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentrations as in the lifetime carcinogenicity study; the high-dose group was exposed to 60 to 74 mg/kg/day of racemic methylphenidate.

Mutagenesis

Dexmethylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay, in the *in vitro* mouse lymphoma cell forward mutation assay, or in the *in vivo* mouse bone marrow micronucleus test. In an *in vitro* assay using cultured Chinese Hamster Ovary cells treated with racemic methylphenidate, sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response.

Impairment of Fertility

No human data on the effect of methylphenidate on fertility are available.

Fertility studies have not been conducted with dexmethylphenidate. Racemic methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week continuous breeding study. The study was conducted at doses of up to 160 mg/kg/day, approximately 10 times the MRHD of 60 mg/day of racemic methylphenidate given to adolescents on a mg/m^2 basis.

14 CLINICAL STUDIES

14.1 Pediatric Patients

A randomized, double-blind, placebo-controlled, parallel-group study (Study 1) was conducted in 103 pediatric patients (ages 6 to 12, n = 86; ages 13 to 17, n = 17) who met DSM-IV criteria for ADHD inattentive, hyperactive-impulsive or combined inattentive/hyperactive-impulsive subtypes (Study 1).

Patients were randomized to receive either a flexible-dose of Focalin XR (5 to 30 mg/day) or placebo once daily for 7 weeks. During the first 5 weeks of treatment, patients were titrated to their optimal dose and remained on this optimal dose for the last 2 weeks of the study without dose changes or interruption.

Signs and symptoms of ADHD were evaluated by comparing the mean change from baseline to endpoint for Focalin XR and placebo-treated patients using an intent-to-treat analysis of the primary efficacy outcome measure, the DSM-IV total subscale score of the Conners ADHD/DSM-IV Scales for teachers (CADS-T). The CADS-T includes the

ADHD Index (12 items) and the DSM-IV total subscale (18 items, total score range: 0 to 54); the latter is divided into inattentive (9 items) and hyperactive-impulsive (9 items) subscales. Teachers assessed behavior observed during the school day by completing the CADS-T weekly. A decrease in the CADS-T DSM-IV total subscale score from baseline indicates improvement.

The CADS-T total scores showed a statistically significant treatment effect in favor of Focalin XR than placebo (Table 6). There were insufficient adolescents enrolled in this study to assess the efficacy for Focalin XR in the adolescent population. However, pharmacokinetic considerations and evidence of effectiveness of immediate-release Focalin in adolescents support the effectiveness of Focalin XR in this population.

Table 6: Summary of Efficacy Results from ADHD Study in Pediatric Patients (6 – 17 years) (Study 1)

Study number	**Treatment group**	**Primary efficacy measure: CADS-T total score**		
		Mean baseline score (SD)	**LS mean change from baseline (SE)**	**Placebo-subtracted difference[a] (95% CI)**
Study 1	Focalin XR 5-30 mg/day (n = 52)	33.3 (9.18)	16.41 (1.8)	10.64 (5.38, 15.91)
	Placebo (n = 45)	34.9 (10.03)	5.77 (1.93)	--

Abbreviations: ADHD, attention deficit hyperactivity disorder; SD, standard deviation; SE, standard error; LS Mean, least-squares mean; CI, confidence interval, not adjusted for multiple comparisons.
[a]Difference (drug minus placebo) in least-squares mean change from baseline.

In 2 additional cross-over studies (Studies 2 and 3) in pediatric patients ages 6 to 12 years, who received 20 mg Focalin XR or placebo, Focalin XR was found to have a statistically significant treatment effect versus placebo on the Swanson, Kotkin, Agler, M-Flynn & Pelham (SKAMP) rating scale total scores at all-time points after dosing in each study (0.5, 1, 3, 4, 5, 7, 9, 10, 11, and 12 hours in Study 2 and 1, 2, 4, 6, 8, 9, 10, 11, and 12 hours in the study 3). SKAMP is a validated 13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting. A treatment effect was also observed 0.5 hours after administration of Focalin XR 20 mg in an additional study of ADHD patients ages 6 to 12 years.

14.2 Adult Patients

A randomized, double-blind, placebo-controlled, parallel-group (Study 4) was conducted in 221 adult patients ages 18 to 60 years who met DSM-IV criteria for ADHD inattentive, hyperactive-impulsive or combined inattentive/hyperactive-impulsive subtypes (Study 4).

Patients were randomized to receive either a fixed dose of Focalin XR (20, 30, or 40 mg/day) or placebo once daily for 5 weeks. Patients randomized to Focalin XR were initiated on a 10 mg/day starting dose and titrated in increments of 10 mg/week to the randomly assigned fixed dose. Patients were maintained on their fixed dose (20, 30, or 40 mg/day) for a minimum of 2 weeks.

Signs and symptoms of ADHD were evaluated by comparing the mean change from baseline to endpoint for Focalin XR and placebo-treated patients using an intent-to-treat analysis of the primary efficacy outcome measure, the investigator-administered DSM-IV Attention-Deficit/Hyperactivity Disorder Rating Scale (DSM-IV ADHD-RS).

The DSM-IV ADHD-RS is an 18-item questionnaire with a score range of 0 to 54 points that measures the core symptoms of ADHD and includes both hyperactive/impulsive and inattentive subscales.

All 3 Focalin XR doses (20, 30, and 40 mg/day) showed a statistically significant treatment effect compared to placebo. There was no obvious increase in effectiveness with increasing the dose.

Table 7: Summary of Efficacy Results from ADHD Study in Adults (Study 4)

Study number	**Treatment group**	**Primary efficacy Measure: ADHD-RS total score**		
		Mean baseline score (SD)	**LS mean change from baseline (SE)**	**Placebo-subtracted difference[a] (95% CI)**
Study 4	Focalin XR 20 mg/day (n = 57)	36.8 (7.2)	13.27 (1.44)	5.71 (1.64, 9.78)
	Focalin XR 30 mg/day (n = 54)	36.9 (8.07)	12.86 (1.48)	5.31 (1.18, 9.44)
	Focalin XR 40 mg/day (n = 54)	36.9 (8.25)	16.51 (1.48)	8.96 (4.83, 13.08)
	Placebo (n = 53)	37.5 (7.82)	7.55 (1.49)	--

Abbreviations: ADHD, attention deficit hyperactivity disorder; SD, standard deviation; SE, standard error; LS Mean, least-squares mean; CI, confidence interval, not adjusted for multiple comparisons.
[a]Difference (drug minus placebo) in least-squares mean change from baseline.

16 HOW SUPPLIED/STORAGE AND HANDLING

Focalin XR (dexmethylphenidate hydrochloride) extended-release capsules are available as follows:

- 5 mg capsules (NDC 66758-235-01) light-blue, (imprinted “SDZ D5”) supplied in bottles of 100
- 10 mg capsules (NDC 66758-236-01) light caramel (imprinted “SDZ D10”) supplied in bottles of 100
- 15 mg capsules (NDC 66758-237-01) green (imprinted “SDZ D15”) supplied in bottles of 100
- 20 mg capsules (NDC 66758-238-01) white (imprinted “SDZ D20”) supplied in bottles of 100

- 25 mg capsules (NDC 66758-239-01) light-blue and white (imprinted “SDZ D25”) supplied in bottles of 100
- 30 mg capsules (NDC 66758-240-01) light caramel and white (imprinted “SDZ D30”) supplied in bottles of 100
- 35 mg capsules (NDC 66758-241-01) light-blue and light caramel (imprinted “SDZ D35”) supplied in bottles of 100
- 40 mg capsules (NDC 66758-242-01) green and white (imprinted “SDZ D40”) supplied in bottles of 100

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Dispense in tight container (USP).

17 PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling (Medication Guide).

Abuse, Misuse, and Addiction

Educate patients and their families about the risks of abuse, misuse, and addiction of Focalin XR, which can lead to overdose and death, and proper disposal of any unused drug *[see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2), Overdosage (10)]*. Advise patients to store Focalin XR in a safe place, preferably locked, and instruct patients to not give Focalin XR to anyone else.

Risks to Patients with Serious Cardiac Disease

Advise patients that there are potential risks to patients with serious cardiac disease, including sudden death, with Focalin XR use. Instruct patients to contact a healthcare provider immediately if they develop symptoms, such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease *[see Warnings and Precautions (5.2)].*

Increased Blood Pressure and Heart Rate

Instruct patients that Focalin XR can cause elevations of their blood pressure and pulse rate *[see Warnings and Precautions (5.3)].*

Psychiatric Adverse Reactions

Advise patients that Focalin XR, at recommended doses, can cause psychotic or manic symptoms, even in patients without prior history of psychotic symptoms or mania *[see Warnings and Precautions (5.4)].*

Priapism

Advise patients of the possibility of painful or prolonged penile erections (priapism). Instruct them to seek immediate medical attention in the event of priapism *[see Warnings and Precautions (5.5)].*

Circulation Problems in Fingers and Toes (Peripheral Vasculopathy, Including Raynaud’s Phenomenon)

Instruct patients beginning treatment with Focalin XR about the risk of peripheral vasculopathy, including Raynaud’s phenomenon, and 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 Focalin XR. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients *[see Warnings and Precautions (5.6)].*

Long-Term Suppression of Growth in Pediatric Patients

Advise patients that Focalin XR may cause slowing of growth and weight loss *[see Warnings and Precautions (5.7)].*

Increased Intraocular Pressure (IOP) and Glaucoma

Advise patients that IOP and glaucoma may occur during treatment with Focalin XR *[see Warnings and Precautions (5.9)].*

Motor and Verbal Tics, and Worsening of Tourette's Syndrome

Advise patients that motor and verbal tics and worsening of Tourette's Syndrome may occur during treatment with Focalin XR. Instruct patients to notify their healthcare provider if emergence of new tics or worsening of tics or Tourette's syndrome occurs *[see Warnings and Precautions (5.10)].*

Pregnancy Registry

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in patients exposed to ADHD medications, including Focalin XR, during pregnancy *[see Use in Specific Populations (8.1)].*

Manufactured by

Societal CDMO Gainesville, LLC

Gainesville, GA 30504 for

Sandoz Inc., Princeton, NJ 08540

PCR-750-18857 US

MEDICATION GUIDE
FOCALIN XR® (foh-kuh-lin XR)
(dexmethylphenidate hydrochloride, USP)
extended-release capsules for oral use, CII

What is the most important information I should know about FOCALIN XR?
FOCALIN XR may cause serious side effects, including:

- Abuse, misuse, and addiction. FOCALIN XR has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of FOCALIN XR, other methylphenidate containing medicines, and amphetamine containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of FOCALIN XR or when it is used in ways that are not approved, such as snorting or injection.

- Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with FOCALIN XR and will monitor you or your child during treatment.
- FOCALIN XR may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
- Do not give FOCALIN XR to anyone else. See "What is FOCALIN XR?" for more information.
- Keep FOCALIN XR in a safe place and properly dispose of any unused medicine. See "How should I store FOCALIN XR?" for more information.
- Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.

- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease.

Your healthcare provider should check you or your child carefully for heart problems before starting FOCALIN XR. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.
Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems, such as chest pain, shortness of breath, or fainting while taking FOCALIN XR.

- **Increased blood pressure and heart rate.** Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with FOCALIN XR.
- **Mental (psychiatric) problems:**

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness
- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.
Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems while taking FOCALIN XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What is FOCALIN XR?

- FOCALIN XR is a central nervous system stimulant (CNS) prescription medicine. It is used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). FOCALIN XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.
- FOCALIN XR should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

Focalin XR is not recommended for use in children under 6 years of age with ADHD.

FOCALIN XR is a federally controlled substance (CII) because it contains dexmethylphenidate that can be a target for people who abuse prescription medicines or street drugs. Keep FOCALIN XR in a safe place to protect it from theft. Never give your FOCALIN XR to anyone else because it may cause death or harm them. Selling or giving away FOCALIN XR may harm others and is against the law.

Who should not take FOCALIN XR?
FOCALIN XR should not be taken if you or your child:

- are allergic to methylphenidate hydrochloride, or any of the ingredients in FOCALIN XR. See the end of this Medication Guide for a complete list of ingredients in FOCALIN XR.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor (MAOI).

FOCALIN XR may not be right for you or your child. Before starting FOCALIN XR, tell your or your child's healthcare provider about all health conditions (or a family history of), including:

- heart problems, heart, disease, heart defects, or high blood pressure
- mental problems, including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome.
- if you are pregnant or plan to become pregnant. It is not known if FOCALIN XR will harm your unborn baby.
    - There is a pregnancy registry for females who are exposed to ADHD medications, including FOCALIN XR, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to FOCALIN XR and their baby. If you or your child becomes pregnant during treatment with FOCALIN XR, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD medications at 1- 866-961-2388 or visit online at https://womensmentalhealth.org/adhd-medications/.
- if you are breastfeeding or plan to breastfeed. FOCALIN XR passes into your breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with FOCALIN XR.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. FOCALIN XR 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 FOCALIN XR.
Your healthcare provider will decide whether FOCALIN XR can be taken with other medicines.
Especially tell your healthcare provider if you or your child takes:

- anti-depression medicines, including MAOIs
- blood pressure medicines (anti-hypertensive)

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

- You should not take FOCALIN XR on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

Do not start any new medicine while taking FOCALIN XR without talking to your healthcare provider first.

How should FOCALIN XR be taken?

- Take FOCALIN XR exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.
- Take FOCALIN XR once each day in the morning. FOCALIN XR is an extended-release capsule.
- FOCALIN XR can be taken with or without food. Taking FOCALIN XR with food may slow the time it takes for the medicine to start working.
- Swallow FOCALIN XR capsules whole with water or other liquids. Do not chew, crush, or divide the capsules or the beads in the capsule. If you or your child cannot swallow the capsule, open it and sprinkle the small beads of medicine over a spoonful of applesauce and swallow it right away without chewing.
- Your healthcare provider may do regular checks of the blood, heart, and blood pressure while taking FOCALIN XR.
- Children should have their height and weight checked often while taking FOCALIN XR. FOCALIN XR treatment may be stopped if a problem is found during these check-ups.

If you or your child take too much FOCALIN XR, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of FOCALIN XR?
FOCALIN XR may cause serious side effects, including:

- see **“What is the most important information I should know about FOCALIN XR?” f**or information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a healthcare provider immediately.
- **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 color from pale, to blue, to red

Tell your healthcare provider if you or your child have, numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

- **Call your healthcare provider right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking FOCALIN XR.**

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with FOCALIN XR. FOCALIN XR treatment may be stopped if your child is not growing or gaining weight.
- **Eye problems (increased pressure in the eye and glaucoma).** Call your healthcare provider right away if you or your child develop changes in your vision or eye pain, swelling, or redness.
- **New or worsening tics or worsening Tourette's syndrome.** Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with FOCALIN XR.

Common side effects include:
Children (6–17 years)

• dyspepsia	• decreased appetite	• headache	• anxiety	

Adults

• dry mouth	• dyspepsia	• headache	• anxiety	• pharyngolaryngeal pain

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 FOCALIN XR?

- Store FOCALIN XR in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Dispose of remaining, unused, or expired FOCALIN XR by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix FOCALIN XR with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container, such as a sealed plastic bag and throw away FOCALIN XR in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicine.
- **Keep FOCALIN XR and all medicines out of the reach of children.**

General information about the safe and effective use of FOCALIN XR.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about FOCALIN XR that is written for healthcare professionals. Do not use FOCALIN XR for a condition for which it was not prescribed. Do not give FOCALIN XR to other people, even if they have the same symptoms that you have. It may harm them and it is against the law.

What are the ingredients in FOCALIN XR?
Active ingredient: dexmethylphenidate hydrochloride
Inactive ingredients: ammonio methacrylate copolymer, gelatin, methacrylic acid copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide, and triethyl citrate.

Each strength capsule also contains colorant ingredients in the capsule shell as follows:
• 5 mg: E132 FD&C Blue No. 2
• 10 mg: FDA/E172 iron oxide yellow
• 15 mg: FD&C Blue No. 2, FDA/E172 iron oxide yellow

• 20 mg: contains no colorants
• 25 mg: E132 FD&C Blue No. 2
• 30 mg: FDA/E172 iron oxide yellow
• 35 mg: E132 FD&C Blue No. 2, FDA/E172 iron oxide yellow
• 40 mg: E132 FD&C Blue No. 2, FDA/E172 iron oxide yellow

Manufactured by
Societal CDMO Gainesville, LLC
Gainesville, GA 30504 for
Sandoz Inc., Princeton, NJ 08540
For more information, call 1-800-525-8747.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised: 09/2025

PRINCIPAL DISPLAY PANEL

NDC 66758-235-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

5 mg

100 capsules

Dispense with Medication Guide attached or provided separately.

SANDOZ

PRINCIPAL DISPLAY PANEL

NDC 66758-236-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

10 mg

100 capsules

Dispense with Medication Guide attached or provided separately.

SANDOZ

PRINCIPAL DISPLAY PANEL

NDC 66758-237-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

15 mg

100 capsules

Dispense with Medication Guide attached or provided separately.

SANDOZ

PRINCIPAL DISPLAY PANEL

NDC 66758-238-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

20 mg

100 capsules

Dispense with Medication Guide attached or provided separately.

SANDOZ

PRINCIPAL DISPLAY PANEL

NDC 66758-239-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

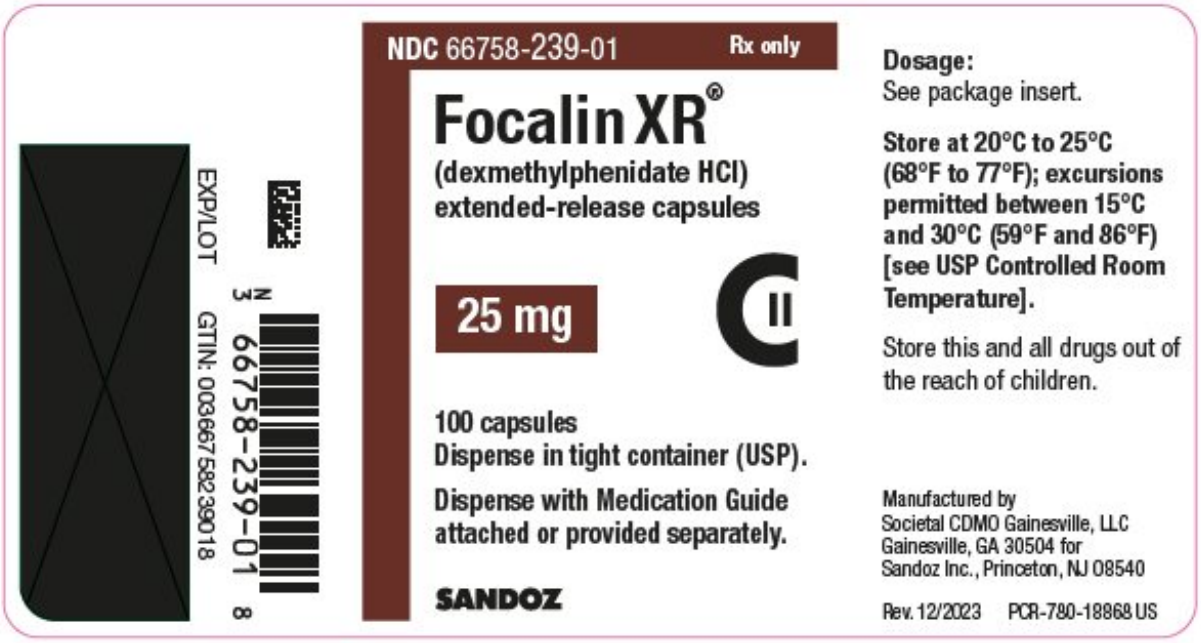
25 mg

100 capsules

Dispense in tight container (USP).

Dispense with Medication Guide
attached or provided separately.

SANDOZ



PRINCIPAL DISPLAY PANEL

NDC 66758-240-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

30 mg

100 capsules

Dispense in tight container (USP).

Dispense with
Medication Guide attached
or provided separately.

SANDOZ

PRINCIPAL DISPLAY PANEL

NDC 66758-241-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

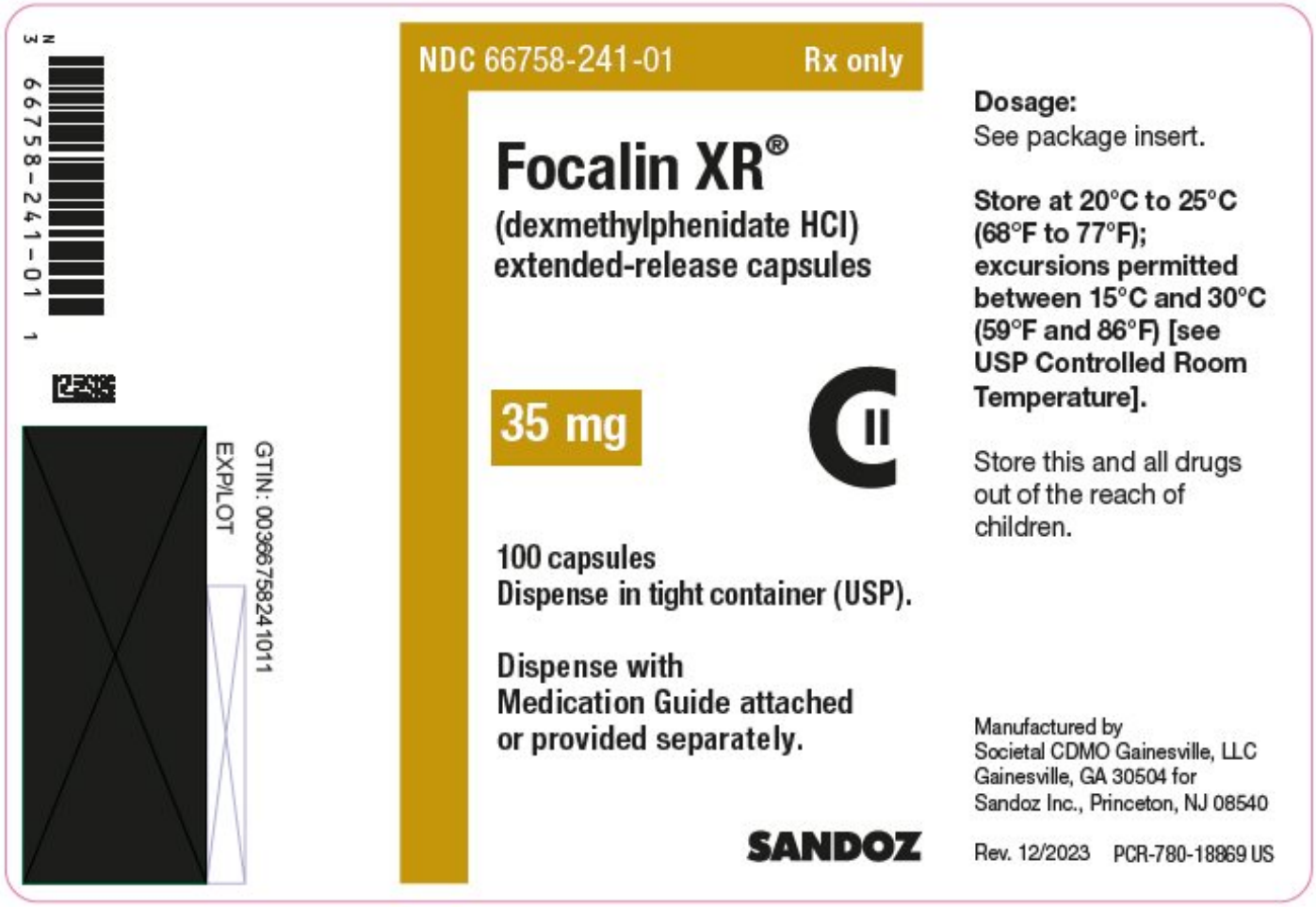
35 mg

100 capsules

Dispense in tight container (USP).

Dispense with
Medication Guide attached
or provided separately.

SANDOZ



PRINCIPAL DISPLAY PANEL

NDC 66758-242-01 Rx only

Focalin XR®

(dexmethylphenidate HCl)

extended-release capsules

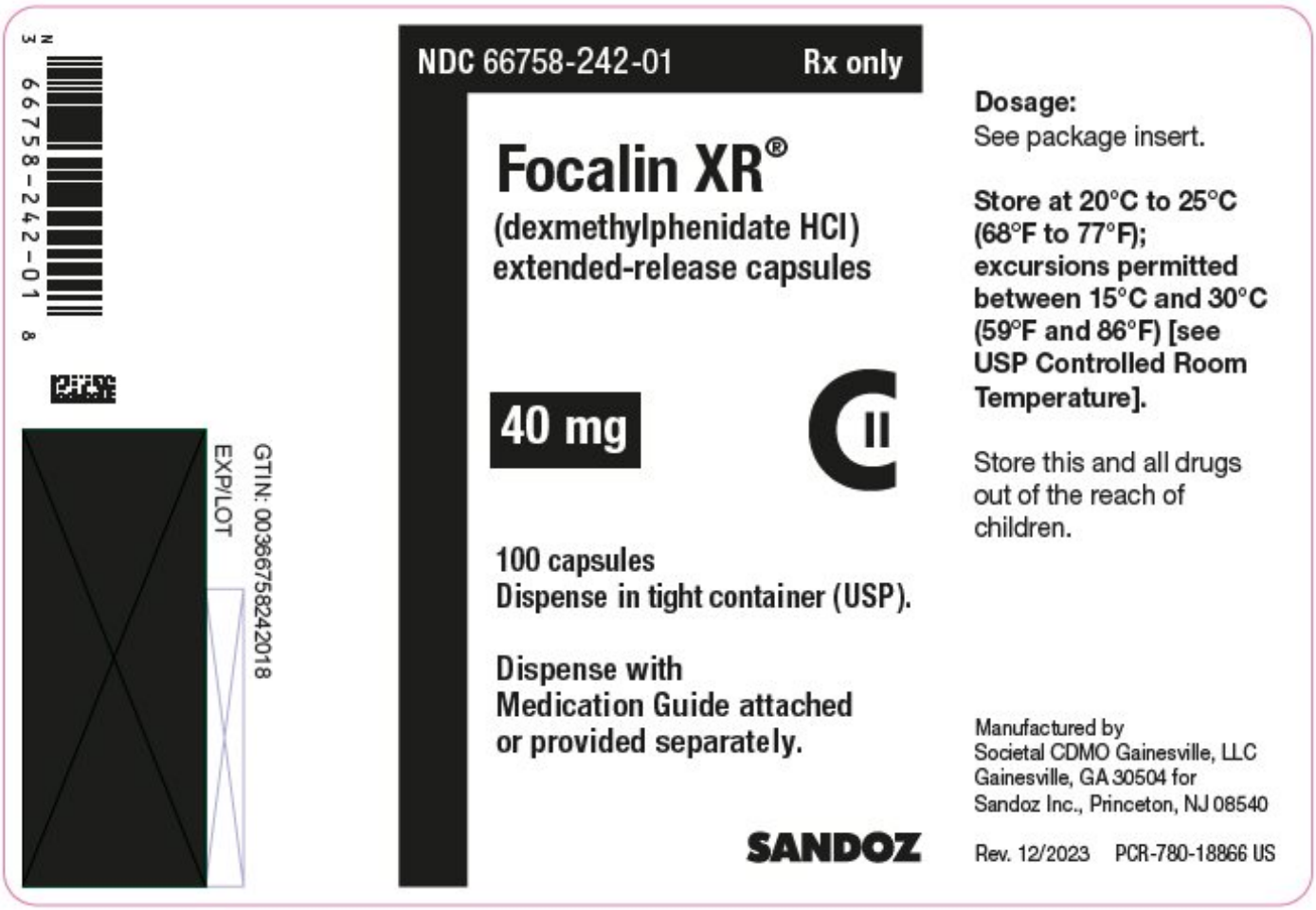
40 mg

100 capsules

Dispense in tight container (USP).

Dispense with
Medication Guide attached
or provided separately.

SANDOZ



FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-240
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	30 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	BROWN, WHITE	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SDZ;D30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-240-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-239
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics			
Color	BLUE (light blue)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SDZ;D25
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66758-239-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-241
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	35 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	BLUE (light blue)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SDZ;D35
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-241-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-242
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	40 mg

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	GREEN, WHITE	**Score**	no score
Shape	CAPSULE	**Size**	19mm

Flavor		**Imprint Code**	SDZ;D40
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:66758-242-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-237
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	15 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	GREEN	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SDZ;D15

Contains	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-237-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-235
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	SDZ;D5
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-235-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-236
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	CAPSULE	**Size**	18mm
Flavor		**Imprint Code**	SDZ;D10
Contains			

Packaging				

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-236-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

FOCALIN XR

dexmethylphenidate hydrochloride capsule, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66758-238
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXMETHYLPHENIDATE HYDROCHLORIDE (UNII: 1678OK0E08) (DEXMETHYLPHENIDATE - UNII:M32RH9MFGP)	DEXMETHYLPHENIDATE HYDROCHLORIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	SDZ;D20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66758-238-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/04/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021802	05/31/2005	

Labeler - Sandoz Inc (005387188)

Revised: 9/2025 Sandoz Inc