METHAMPHETAMINE HYDROCHLORIDE- methamphetamine hydrochloride tablet
Dr. Reddy's Laboratories Inc

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use METHAMPHETAMINE HYDROCHLORIDE TABLETS, USP safely and effectively. See full prescribing information for METHAMPHETAMINE HYDROCHLORIDE TABLETS, USP.
METHAMPHETAMINE HYDROCHLORIDE TABLETS, USP, for oral use, CII
Initial U.S. Approval: 1943

WARNING: ABUSE, MISUSE, AND ADDICTION
See full prescribing information for complete boxed warning.

METHAMPHETAMINE 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 METHAMPHETAMINE, can result in overdose and death. (5.1, 9.2, 10):

- **Before prescribing METHAMPHETAMINE, assess each patient's risk for abuse, misuse, and addiction.**
- **Educate patients and their families about these risks, proper storage of each 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.**

INDICATIONS AND USAGE

Methamphetamine hydrochloride tablets, USP is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 years of age and older. (1)

DOSAGE AND ADMINISTRATION

- Administer methamphetamine hydrochloride tablets, USP orally once daily or in two divided doses daily. Avoid administration late in the evening due to the risk of insomnia. (2.2)
- Recommended starting dosage is 5 mg once or twice a daily. (2.3)
- Daily dosage may be increased in 5 mg increments at weekly intervals depending on clinical response. (2.3)
- The recommended dosage range is 20 mg to 25 mg daily. (2.3)

DOSAGE FORMS AND STRENGTHS

Tablets: 5 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to amphetamine, or other components of methamphetamine hydrochloride tablets, USP. (4)
- Concomitant use of monoamine oxidase inhibitors (MAOIs), 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 methamphetamine hydrochloride tablets, USP, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing methamphetamine hydrochloride tablets, USP (5.4)
- 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. (5.5)
- Peripheral Vasculopathy, including Raynaud's Phenomenon: Careful observation for digital changes is necessary during methamphetamine treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy. (5.6)
- Seizures: May lower the convulsive threshold. If a seizure occurs, discontinue methamphetamine hydrochloride tablets, USP. (5.7)
- Serotonin Syndrome: Increased risk when coadministered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), but also during overdosage situations. If it occurs, discontinue methamphetamine hydrochloride tablets, USP and initiate supportive treatment. (5.8)
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating methamphetamine hydrochloride tablets, USP, 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. (5.9)

ADVERSE REACTIONS

Common adverse reactions include: palpitation, dizziness, insomnia, tremor, headache, diarrhea, dryness of mouth. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Dr. Reddy's Laboratories at 1-888-375-3784 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. (6)

DRUG INTERACTIONS

Acidifying and Alkalinizing Agents: Agents that alter GI and urinary pH can alter blood levels of amphetamine. Acidifying agents can decrease amphetamine blood levels, while alkalinizing agents can increase amphetamine blood levels. (7.1)

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm. (8.1)
- Lactation: Breastfeeding not recommended. (8.2)

See 17 for Medication Guide.

Revised: 10/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

METHAMPHETAMINE 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 METHAMPHETAMINE, 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 METHAMPHETAMINE, 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 METHAMPHETAMINE 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)* **and** *Drug Abuse and Dependence (9.2)***].**

1. INDICATIONS AND USAGE

Methamphetamine hydrochloride tablets, USP is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 years of age and older.

2. DOSAGE & ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating patients with methamphetamine hydrochloride tablets, USP, assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical examination) *[see Warnings and Precautions (5.2)].*
- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome before initiating methamphetamine hydrochloride tablets, USP *[see WARNINGS AND PRECAUTIONS (5.9)].*

2.2 Important Dosing Information

Administer methamphetamine hydrochloride tablets, USP orally once daily or in two divided doses daily. Avoid taking methamphetamine hydrochloride tablets, USP late in the evening due to the risk of insomnia.

2.3 Recommended Dosage

For pediatric patients 6 years of age and older, the recommended starting dosage is 5 mg methamphetamine hydrochloride tablets, USP once or twice daily. The daily dosage may be increased in increments of 5 mg at weekly intervals based on clinical response of the patient. The recommended dosage range is 20 mg to 25 mg daily.

2.4 Dosage Modifications Due to Drug Interactions

Agents that alter urinary pH can impact excretion and alter blood levels of amphetamine. Acidifying agents (e.g., ascorbic acid) decrease blood levels, while alkalinizing agents (e.g., sodium bicarbonate) increase blood levels. Adjust methamphetamine dosage based on clinical response *[see Drug Interactions (7.1)].*

3. DOSAGE FORMS AND STRENGTHS

Tablets: 5 mg of methamphetamine hydrochloride as white, round, unscored tablets debossed with 115 on one side of the tablet and blank on the other side.

4. CONTRAINDICATIONS

Methamphetamine hydrochloride tablets, USP is contraindicated in patients with:

- known hypersensitivity to amphetamine, or other components of methamphetamine. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other amphetamine products *[see Adverse Reactions (6)].*
- taking monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of treatment with an MAOIs (including MAOIs such as linezolid or intravenous methylene blue), because of the risk of hypertensive crisis *[see Drug Interactions (7.1)].*

5. WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Methamphetamine has a high potential for abuse and misuse. The use of methamphetamine exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Methamphetamine can be diverted for non-medical use into illicit channels or distribution [see Drug Abuse and Dependence (9.2, 9.3)]. Misuse and abuse of CNS stimulants, including methamphetamine, 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 methamphetamine, 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 methamphetamine in a safe place, preferably locked, and instruct patients to not give methamphetamine to anyone else. Throughout methamphetamine 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 and other serious cardiac disease who were treated with CNS stimulants at recommended ADHD dosage.

Avoid methamphetamine use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart arrhythmia, coronary artery disease, and other serious heart problems.

5.3 Increased Blood Pressure and Heart Rate

CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Some patients may have larger increases.

Monitor all methamphetamine-treated patients for potential tachycardia and hypertension *[see Adverse Reactions (6)].*

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 Illness

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

New Psychotic or Manic Symptoms

CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without 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 0.1% of CNS stimulant-treated patients compared to 0% in placebo-treated patients. If such symptoms occur, consider discontinuing methamphetamine.

5.5 Long-Term Suppression of Growth in Pediatric Patients

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in methamphetamine-treated pediatric patients treated with CNS stimulants.

Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon

CNS stimulants, including methamphetamine, used to treat ADHD are associated with peripheralvasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration 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 CNS stimulant.

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

5.7 Seizures

Methamphetamine may lower the convulsive threshold in patients with prior history of seizure, in patients with prior EEG abnormalities in the absence of seizures, and in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, methamphetamine should be discontinued.

5.8 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 monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort *[see Drug Interactions (7.1)].* The coadministration with cytochrome P450 2D6 (CYP2D6) inhibitors may also increase the risk with increased exposure to methamphetamine. In these situations, consider an alternative
nonserotonergic 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, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea).

Concomitant use of methamphetamine
with MAOI drugs is contraindicated *[see Contraindications (4)].*

Discontinue treatment with methamphetamine
and any concomitant serotonergic agents immediately if
the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of methamphetamine with other serotonergic drugs or CYP2D6 inhibitors is clinically warranted, initiate methamphetamine with lower doses, monitor patients for the emergence of serotonin syndrome during drug initiation or titration, and inform patients of the increased risk for serotonin syndrome.

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

CNS stimulants, including amphetamine, 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)].*

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

6. ADVERSE REACTIONS

The following adverse reactions are discussed in greater 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)]*
- Hypersensitivity to amphetamine products or other ingredients of methamphetamine [*see Contraindications (4)]*
- Hypertensive Crisis When Used Concomitantly with Monoamine Oxidase Inhibitors *[see Contraindications (4), Drug Interactions (7.1)]*
- Risks to Patient 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)]*
- Long-Term Suppression of Growth in Pediatric Patients*[see Warnings and Precautions (5.5)]*

- Peripheral Vasculopathy, including Raynaud's Phenomenon *[see Warnings and Precautions (5.6)]*
- Seizures [*see Warnings and Precautions (5.7)]*
- Serotonin Syndrome *[see Warnings and Precautions (5.8)]*
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome*[see Warnings and Precautions (5.9)]*

The following adverse reactions associated with the use of methamphetamine were identified in clinical trials or postmarketing reports. Because these reactions were 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.

Cardiovascular: Elevation of blood pressure, tachycardia and palpitation. Fatal cardiorespiratory arrest has been reported, mostly in the context of abuse/misuse

Central Nervous System: Psychotic episodes reported at recommended doses. Dizziness,
dysphoria, overstimulation, euphoria, insomnia, tremor, restlessness and headache. Exacerbation of motor and verbal tics and Tourette's syndrome

Gastrointestinal: Diarrhea, constipation, dryness of mouth, unpleasant taste, intestinal ischemia, and other gastrointestinal disturbances

Hypersensitivity: Urticaria

Endocrine: Impotence and changes in libido; frequent or prolonged erections

Musculoskeletal: Rhabdomyolysis

Metabolism and Nutrition Disorders: Suppression of growth has been reported with the long-term use of stimulants in pediatric patients

Skin and Subcutaneous Tissue Disorders: Alopecia

The following additional adverse reactions have been identified during post approval use of amphetamines:

Allergic: Rash, hypersensitivity reactions, including angioedema and anaphylaxis. Serious skin rashes, including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported.

Cardiovascular: Dyspnea, sudden death, myocardial infarction. There have been isolated reports of cardiomyopathy associated with chronic amphetamine use

Central Nervous System: dyskinesia, fatigue, aggression, anger, logorrhea, dermatillomania, and paresthesia (including formication)

Eye Disorders: Mydriasis

Vascular Disorders: Raynaud's phenomenon

7. DRUG INTERACTIONS

7.1 Drugs Having Clinically Important Interactions with methamphetamine hydrochloride tablets, USP

Table 1 presents clinically important drug interactions with methamphetamine hydrochloride tablets, USP .

Table 1: Clinically Important Drug Interactions with methamphetamine hydrochloride tablets, USP

Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact:	MAOI antidepressants slow amphetamine metabolism, increasing amphetamines effect on the release of norepinephrine and other monoamines from adrenergic nerve endings causing headaches and other signs of hypertensive crisis. Toxic neurological effects and malignant hyperpyrexia can occur, sometimes with fatal results.
Intervention:	Concomitant use of methamphetamine hydrochloride tablets, USP with monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuing MAOI treatment is contraindicated [see Contraindications (4)].
Serotonergic Drugs	
Clinical Impact:	The concomitant use of amphetamines, including methamphetamine hydrochloride tablets, USP , and serotonergic drugs increases the risk of serotonin syndrome.
	Initiate methamphetamine hydrochloride tablets, USP with lower doses and

Intervention:	monitor patients for signs and symptoms of serotonin syndrome, particularly during methamphetamine hydrochloride tablets, USP initiation or dosage increase. If serotonin syndrome occurs, discontinue methamphetamine hydrochloride tablets, USP and the concomitant serotonergic drug(s) [see Warnings and Precautions 5.8].
AlkalinizingAgents	
Clinical Impact:	Alkalinizing agents may increase exposure to amphetamines and potentiate the action of amphetamine.
Intervention	Avoid co-administration of methamphetamine hydrochloride tablets, USP and gastrointestinal and urinary alkalinizing agents.
Acidifying Agents	
Clinical Impact:	Acidifying agents lower blood levels and efficacy of amphetamines.
Intervention	Increase dose of methamphetamine hydrochloride tablets, USP based on clinical response.
Tricyclic Antidepressants	
Clinical Impact:	May enhance the activity of tricyclic or sympathomimetic agents causing sustained increases in the concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated.
Intervention	Monitor frequently and adjust methamphetamine hydrochloride tablets, USP dose or use alternative therapy based on clinical response.
CYP2D6 Inhibitors	
Clinical Impact:	Concomitant use of methamphetamine hydrochloride tablets, USP and CYP2D6 inhibitors may increase the exposure of methamphetamine hydrochloride tablets, USP compared to the use of the drug alone, and increase the risk of serotonin syndrome.
Intervention	Start with lower doses and monitor patients for signs and symptoms of serotonin syndrome particularly during methamphetamine hydrochloride tablets, USP initiation and after a dosage increase. If serotonin syndrome occurs, discontinue methamphetamine hydrochloride tablets, USP and the CYP2D6 inhibitor [see Warnings and Precautions 5.8].
Gastric pH Modulators	
Clinical Impact:	Time to maximum concentration (Tmax) of amphetamine is decreased compared to when administered alone.
Intervention	Monitor patients for changes in clinical effect and use alternative therapy based on clinical response.
Guanethidine	
Clinical Impact:	Methamphetamine may decrease the hypotensive effect ofguanethidine.
Intervention	Monitor patients and adjust therapy based on clinicalresponse.

Insulin requirements in diabetes mellitus may be altered in association with the use of methamphetamine and the concomitant dietary regimen.

7.2 Drug/Laboratory Test Interactions

Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening. Amphetamines may interfere with urinary steroid determinations.

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 methamphetamine hydrochloride tablets, USP , during pregnancy. Healthcare providers are encouraged to advise patients to register by contacting the National Pregnancy Registry for ADHD Medications at 1- 866-961-2388 or visiting online at www.womensmentalhealth.org/research/pregnancyregistry/adhd-medications/.

Risk Summary

Available data from epidemiologic studies and postmarketing reports on use of methamphetamine and amphetamine in pregnant women over decades of use have not identified

a drug-associated risk of major birth defects or miscarriage. Neonates exposed to amphetamines in utero are at risk for withdrawal symptoms following delivery. 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).*

In animals, administration of methamphetamine during organogenesis resulted in developmental toxicity, including neonatal death and fetal malformations, at doses equivalent to the maximum recommended human dose (MRHD) on a mg/m^2 basis. Oral administration of methamphetamine to rats during pregnancy, pregnancy and lactation, or lactation resulted in developmental toxicity in the offspring, including, neonatal mortality and delayed development, at a maternal dose similar to the MRHD on a mg/m^2 basis.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of 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 methamphetamine hydrochloride tablets, USP , cause vasoconstriction and thereby 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 methamphetamine for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive drowsiness.

Data

Animal Data

Based on published data, methamphetamine administration during the period of organogenesis caused malformations and pup mortality in mammals at doses equivalent to the maximum recommended human dose (MRHD) on a mg/m2 basis. Oral administration of methamphetamine (0, or 3.75 mg/kg) to pregnant rats during gestation, throughout gestation and lactation, or only during lactation resulted in an increase in neonatal pup mortality. Delayed somatic development (pinna unfolding and eye opening) and impairments in neurobehavioral development (righting reflex, incline plane test, and forelimb grip strength) were observed in the pups. The dose with adverse effects was equivalent to the MRHD of 25 mg on a mg/m^2 basis.

8.2 Lactation

Risk Summary

Based on limited case reports in the published literature, methamphetamine and its active metabolite, amphetamine, are present in human milk. There are no reports of adverse effects on the breastfed infant. Long-term neurodevelopmental effects on infants from amphetamine exposure are unknown. It is possible that large doses of amphetamine might interfere with milk production, especially in women whose lactation is not well established. Because of the potential for serious adverse reactions in nursing infants, advise patients that breastfeeding is not recommended during treatment with methamphetamine hydrochloride tablets, USP .

8.4 Pediatric Use

The safety and effectiveness of methamphetamine hydrochloride tablets, USP for the treatment of ADHD have been established in pediatric patients aged 6 years and older.

The safety and effectiveness of methamphetamine hydrochloride tablets, USP have not been established in pediatric patients younger than 6 years old.

Growth Suppression

Growth should be monitored during treatment with stimulants, including methamphetamine hydrochloride tablets, USP. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted *[see Warnings and Precautions (5.5), Adverse Reactions (6)].*

8.5 Geriatric Use

Clinical studies of methamphetamine hydrochloride tablets, USP did not include sufficient numbers of subjects age 65 years and over to determine whether elderly subjects respond differently from younger subjects.

9. DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Methamphetamine hydrochloride tablets, USP contains methamphetamine hydrochloride, a Schedule II controlled substance.

9.2 Abuse

Methamphetamine 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)]*. Methamphetamine 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 methamphetamine 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 Methamphetamine, 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

Methamphetamine 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 methamphetamine include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Methamphetamine 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.

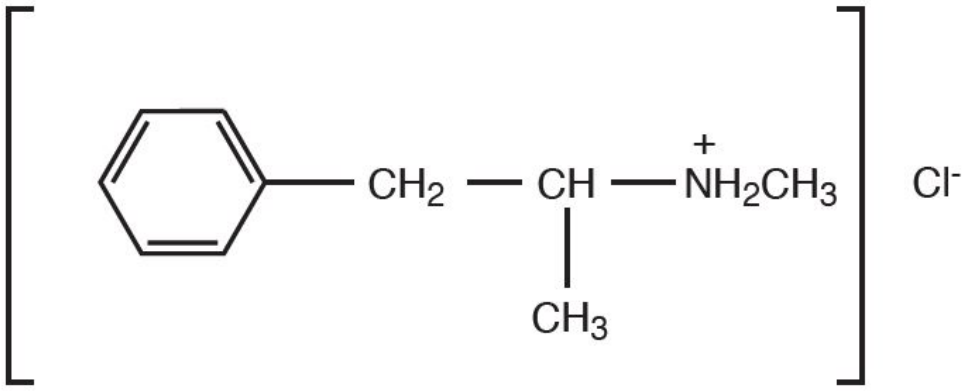
Overdose Management

Consider the possibility of multiple drug ingestion. D-amphetamine is not dialyzable.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11. DESCRIPTION

Methamphetamine hydrochloride tablets, USP contain methamphetamine, a central nervous system stimulant, in the form of hydrochloride salt. Methamphetamine hydrochloride is chemically known as (S) N,α dimethylbenzeneethanamine hydrochloride with molecular formula of C10H15N.HCl and molecular weight of 185.73 g/mol It has the following structural formula:



Methamphetamine hydrochloride tablets, USP contain 5 mg of methamphetamine hydrochloride, USP for oral administration.

Inactive Ingredients:

Corn starch, lactose monohydrate, stearic acid and talc.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. The exact mode of therapeutic action in the treatment of 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

Absorption

Methamphetamine is absorbed from the gastrointestinal tract.

Elimination

Metabolism

The primary site of metabolism is in the liver by aromatic hydroxylation, N-dealkylation and
deamination. At least seven metabolites have been identified in the urine. The biological half-life has been reported in the range of 4 to 5 hours.

Excretion

Excretion occurs primarily in the urine and is dependent on urine pH. Alkaline urine will significantly increase the drug half-
life. Approximately 62% of an oral dose is eliminated in the urine within the first 24 hours with about one-third as intact drug and the remainder as metabolites.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity and Mutagenesis

Carcinogenicity, mutagenic, or genotoxic potential of methamphetamine has not been fully characterized.

Impairment of Fertility

There have been no adequate studies performed in animals at current standards to evaluate the effect of methamphetamine treatment on fertility. However, published studies in mice and rats exposed to repeated daily dosing of methamphetamine report irregular estrous cycling and decreased ovarian reserve in females, and decreased sperm density, motility, and percent of sperm with normal morphology in males. The clinical significance of these findings is not clear.

16. HOW SUPPLIED /STORAGE AND HANDLING

How Supplied

Methamphetamine hydrochloride tablets, USP are available containing 5 mg of methamphetamine hydrochloride, USP.

The 5 mg tablets are white, round, unscored tablets debossed with 115 on one side of the tablet and blank on the other side. They are available as follows:

NDC 75907-094-01
bottles of 100 tablets

Storage and Handling

Store at 20º to 25ºC (68º to 77ºF). [See USP Controlled Room Temperature.]
Protect from light.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

17. PATIENT COUNSELING INFORMATION

Advise the patient 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 methamphetamine hydrochloride tablets, USP , 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 methamphetamine hydrochloride tablets, USP in a safe place, preferably locked, and instruct patients to not give methamphetamine hydrochloride tablets, USP 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 methamphetamine hydrochloride tablets, USP 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 methamphetamine hydrochloride tablets, USP can cause elevations of their blood pressure and pulse rate and they should be monitored for such effects *[see Warnings and Precautions (5.3)].*

Psychiatric Adverse Risks

Advise patients that methamphetamine hydrochloride tablets, USP , at recommended doses, may cause psychotic or manic symptoms even in patients without prior history of psychotic symptoms or mania *[see Warnings and Precautions (5.4)].*

Long-Term Suppression of Growth in Pediatric Patients

Advise patients, family members, and caregivers that methamphetamine hydrochloride tablets, USP may cause slowing of growth including weight loss *[see Warnings and Precautions (5.5)].*

Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon)

Instruct patients beginning treatment with methamphetamine hydrochloride tablets, USP 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 methamphetamine hydrochloride tablets, USP . Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients *[see Warnings and Precautions (5.6)].*

Seizures

Caution patient that methamphetamine hydrochloride tablets, USP may lower the convulsive threshold. Advise patients to contact their healthcare provider immediately and to discontinue methamphetamine hydrochloride tablets, USP if a seizure occurs *[see Warnings and Precautions (5.7)].*

Serotonin Syndrome

Caution patients about the risk of serotonin syndrome with concomitant use of methamphetamine hydrochloride tablets, USP and other serotonergic drugs including SSRIs, SNRIs, triptans, tricyclic antidepressants, fentanyl,lithium, tramadol, tryptophan, buspirone, St. 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 (5.8) 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.

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 methamphetamine hydrochloride tablets, USP . Instruct patients to notify their healthcare provider ifemergence of new tics or worsening of tics or Tourette's syndrome occurs *[see Warnings and Precautions (5.9)].*

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)].*

Pregnancy

Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to methamphetamine hydrochloride tablets, USP during pregnancy. Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with methamphetamine hydrochloride tablets, USP . Advise patients of the potential fetal effects from the use of methamphetamine hydrochloride tablets, USP during pregnancy *[see Use in Specific Populations (8.1)].*

Lactation

Advise patients not to breastfeed if they are taking methamphetamine hydrochloride tablets, USP *[see Use in Specific Populations (8.2)].*

Distributed by:

Dr. Reddy's Laboratories Inc.

Princeton, NJ08540

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MEDICATION GUIDE

METHAMPHETAMINE HYDROCHLORIDE TABLETS, USP CII
(metham-fetă-mēn hīdrŏ-klōrīd)

5 mg

What is the most important information I should know about methamphetamine hydrochloride tablets?
Methamphetamine hydrochloride tablets may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Methamphetamine hydrochloride tablets has a high chance for abuse and misuse and
  may lead to substance use problems, including addiction. Misuse and abuse of Methamphetamine

hydrochloride tablets, other amphetamine containing medicines, and methylphenidate containing medicines, can
lead to overdose and death. The risk of overdose and death is increased with higher doses of Methamphetamine hydrochloride tablets or when it is used in ways that are not approved, such as snorting or injection.
  - Your healthcare provider should check your child's risk for abuse, misuse, and addiction before starting treatment with Methamphetamine hydrochloride tablets and will monitor your child during treatment.
  - Methamphetamine hydrochloride
tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give Methamphetamine Hydrochloride
tablets to anyone else. See **"What is Methamphetamine hydrochloride tablets?**" for more information.
  - Keep Methamphetamine Hydrochloride
tablets in a safe place and properly dispose of any unused medicine. See "**How should I store Methamphetamine hydrochloride tablets?**" for more information.
  - Tell your healthcare provider if your child has 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 whohave heart defects or other serious heart disease.

Your child's healthcare provider should check your child carefully for heart problems before starting treatment with Methamphetamine hydrochloride tablets. Tell your child's healthcare provider if your child has any heart problems, heart disease, or heart defects.
Call your child's healthcare provider or go to the nearest hospital emergency room right away if your child has any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with Methamphetamine Hydrochloride tablets.
- **Increased blood pressure and heart rate**. Your child's healthcare provider should check your child's blood pressure and heart rate regularly during treatment with Methamphetamine hydrochloride tablets.

- **Mental (Psychiatric) problems, inlcudin**

- - new or worse behavior and thought problems
  - new orworse bipolarillness
  - newpsychoticsymptoms(suchashearingvoices or seeing orbelievingthingsthatarenot real) or new manic symptoms

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

Call your child's healthcare provider right away if your child has any new or worsening mental symptoms or problems during treatment with Methamphetamine hydrochloride tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are Methamphetamine hydrochloride tablets?

Methamphetamine hydrochloride tablets are a central nervous system (CNS) stimulant prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years to 17 years of age. Methamphetamine hydrochloride tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.It is not known if Methamphetamine hydrochloride tablets is safe and effective in children under 6 years of age.

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

Do not take Methamphetamine hydrochloride tablets if your child is:
- allergic to amphetamine or any of the ingredients in Methamphetamine hydrochloride tablets. See the end of this Medication Guide for a complete list of ingredients in Methamphetamine hydrochloride tablets.
- taking, or has stopped taking within the past 14 days, a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).

**Before taking Methamphetamine hydrochloride
tablets, tell your child's healthcare provider about all your child's medical**

conditions, including if your child:

- has heart problems, heart disease, heart defects, or high blood pressure
- has mental problems including psychosis, mania, bipolar illness or depression, or a family history of suicide bipolar illness, or depression
- has circulation problems in fingers and toes
- has kidney problems
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- has pregnant or plans to become pregnant.It is not known if methamphetamine hydrochloride tabletswill harm the unborn baby.
  - There is a pregnancy registry for femles who are exposed to Methamphetamine hydrochloride tablets during pregnancy. The purpose of the registry is to collect information about the health of females exposed to Methamphetamine hydrochloride tablets and their baby. If your child becomes pregnant during treatment with Methamphetamine hydrochloride tablets, talk to your child's healthcare provider about registering with the National Pregnancy Registry for Psychostimulants. You can register by calling 1-866-961- 2388 or by visiting online at https://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/othermedications/
- is breastfeeding or plans to breastfeed. Methamphetamine hydrochloride tablets passes into breast milk. Your child should not breastfeed during treatment with Methamphetamine hydrochloride tablets. Talk to your child's healthcare provider about the best way to feed the baby during treatment with Methamphetamine hydrochloride tablets.

Tell your child's healthcare provider about all of the medicines that your child takes including prescription and over-the-counter medicines, vitamins, and herbalsupplements.

Methamphetamine hydrochloride tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with Methamphetamine hydrochloride tablets. Your child's healthcare provider will decide whether Methamphetamine hydrochloride tablets can be taken with other medicines.

Especially tell your child's healthcare provider if your child takes:

- medicines used to treat migraine headaches known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- St. John's Wort
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)

Ask your child's healthcare provider if you are not sure if your child takes any of these medicines. Know the medicines your child takes. Keep a list of your child's medicines with you to show your child's healthcare provider and pharmacist. **Do not start any new medicine during treatment with Methamphetamine hydrochloride tablets without talking to your child's healthcare provider first.**

How should Methamphetamine hydrochloride tablets be taken?

- Take Methamphetamine hydrochloride tablets exactly as prescribed.
- Your child's healthcare provider may change the dose or have your child stop taking Methamphetamine hydrochloride tablets if needed.
- Methamphetamine hydrochloride tablets is usually taken 1 or 2 times each day. Avoid taking Methamphetamine late in the evening because it may cause sleep problems.

If your child takes too much Methamphetamine hydrochloride tablets, call your child's healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are possible side effects of Methamphetamine hydrochloride tablets?Methamphetamine hydrochloride tablets may cause serious side effects, including:

- See **"What is the most important information I should know about Methamphetamine**

hydrochloride tablets?"

- **Slowing of growth (height and weight) in children**. Children should have their height and weight checked often during treatment with Methamphetamine hydrochloride tablets. Methamphetamine hydrochloride tablets treatment may be stopped if your child is not growing or gaining weight.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon)**. Signs and symptoms may include:
  - fingers or toes may feel numb, cool, painful
  - fingers or toes may change color from pale, to blue, to red

Tell your child's healthcare provider if your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes or if your child has any signs of unexplained wounds appearing on fingers or toes during treatment with Methamphetamine hydrochloride tablets.

- **Serotonin syndrome**. This problem may happen when Methamphetamine hydrochloride tablets is taken with certain other medicines and may be life-threatening. Call your healthcare provider or go to the nearest hospital emergency room if you have any of the following symptoms of serotonin syndrome:
  - agitation, hallucinations, coma
  - changes in blood pressure
  - high body temperature
  - dizziness
  - sweating or fever
  - muscle stiffness or tightness
  - fast heartbeat
  - flushing
  - seizures
  - nausea, vomiting, diarrhea
  - loss of coordination
  - confusion
- **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 Methamphetamine hydrochloride tablets.

The most common side effects with Methamphetamine hydrochloride tablets include:

- fast heartbeat or heart beating harder than normal
- dizziness
- trouble sleeping
- shaking
- headache
- diarrhea
- dry mouth

These are not all the possible side effects of Methamphetamine hydrochloride tablets.

Call your child's healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or Dr. Reddy's Laboratories at 1-888-375-3784.

How should I store Methamphetamine hydrochloride tablets?

- Store Methamphetamine hydrochloride tablets at room temperature between 68°F to 77°F (20°C to -25°C).
- Store Methamphetamine hydrochloride tablets in a safe place like a locked cabinet. Protect from light.
- Dispose of remaining, unused, or expired Methamphetamine hydrochloride tablets 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 Methamphetamine hydrochloride tablets 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 Methamphetamine hydrochloride tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep Methamphetamine hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of Methamphetamine hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Methamphetamine hydrochloride tablets for a condition for which it was not prescribed. Do not give Methamphetamine hydrochloride tablets to other people, even if they have the same symptoms that your child has. It may harm them and it is against the law.

You can ask your child's pharmacist or healthcare provider for information about Methamphetamine hydrochloride tablets that is written for healthcare professionals.

What are the ingredients in Methamphetamine hydrochloride tablets?

Active Ingredient: methamphetamine hydrochloride, USP

Inactive Ingredients: corn starch, lactose monohydrate, stearic acid and talc

Distributed by:

Dr. Reddy's laboratories Inc.

Princeton, NJ 08540

Rev. 10/2024

PRINCIPAL DISPLAY PANEL - 5 mg Tablet Bottle Label

NDC 75907-094-01

Methamphetamine
Hydrochloride
Tablets, USP

CII

5 mg

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

Rx Only

100 Tablets

Dr. Reddy's Laboratories, Inc

METHAMPHETAMINE HYDROCHLORIDE

methamphetamine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75907-094
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHAMPHETAMINE HYDROCHLORIDE (UNII: 997F43Z9CV) (Methamphetamine - UNII:44RAL3456C)	METHAMPHETAMINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
starch, corn (UNII: O8232NY3SJ)	
lactose monohydrate (UNII: EWQ57Q8I5X)	
stearic acid (UNII: 4ELV7Z65AP)	
talc (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	115
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75907-094-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/07/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091189	11/07/2025	

Labeler - Dr. Reddy's Laboratories Inc (802315887)

Registrant - Dr. Reddy’s Laboratories SA (483733079)

Establishment

Name	Address	ID/FEI	Business Operations
Catalent Greenville, Inc.		118812386	manufacture(75907-094) , analysis(75907-094) , label(75907-094) , pack(75907-094)

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