METHYLPHENIDATE HYDROCHLORIDE- methylphenidate hydrochloride solution
Bryant Ranch Prepack

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use METHYLPHENIDATE HYDROCHLORIDE ORAL SOLUTION safely and effectively.
See full prescribing information for METHYLPHENIDATE HYDROCHLORIDE ORAL SOLUTION.

METHYLPHENIDATE HYDROCHLORIDE Oral Solution, CII
Initial U.S. Approval: 1955

WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

Methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution, can result in overdose and death (5.1, 9.2, 10):

- **Before prescribing methylphenidate hydrochloride oral solution, 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

Boxed Warning	10/2023
Dosage and Administration (2.1, 2.2, 2.3)	10/2023
Warnings and Precautions (5.1, 5.2, 5.8, 5.9, 5.10)	10/2023

INDICATIONS AND USAGE

Methylphenidate hydrochloride oral solution is a central nervous system (CNS) stimulant indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older (1)
- Narcolepsy (1)

DOSAGE AND ADMINISTRATION

- *Pediatric patients 6 years and older:* Starting dose is 5 mg twice daily (before breakfast and lunch); increase the dose 5 mg to 10 mg weekly; daily dosage above 60 mg is not recommended. (2.2)
- *Adults:* Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Maximum recommended daily dosage is 60 mg. (2)

DOSAGE FORMS AND STRENGTHS

Oral solution: 5 mg per 5 mL and 10 mg per 5 mL. (3)

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride oral solution (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 methylphenidate hydrochloride oral solution, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur,

consider discontinuing methylphenidate hydrochloride oral solution. (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 methylphenidate hydrochloride 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 (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:* Methylphenidate hydrochloride-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 methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution, 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

Common adverse reactions: tachycardia, palpitations, headache, insomnia, anxiety, hyperhidrosis, weight loss, decreased appetite, dry mouth, nausea, and abdominal pain. (6)

To report SUSPECTED ADVERSE REACTIONS contact Tris Pharma, Inc., at (732) 940 0358 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: 5/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

Methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride, 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 methylphenidate hydrochloride oral solution, 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 methylphenidate hydrochloride oral solution 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

Methylphenidate hydrochloride oral solution is indicated for the treatment of:

• Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years of age and older

• Narcolepsy

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating patients with methylphenidate hydrochloride oral solution, 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 *[see Warnings and Precautions (5.10)]*.

2.2 General Dosing Information

Pediatric Patients 6 years of Age and Older

The recommended starting dosage is 5 mg orally twice daily before breakfast and lunch (preferably 30 to 45 minutes before meals). Increase the dosage gradually, in increments of 5 mg to 10 mg weekly.

Daily dosage above 60 mg is not recommended.

Adults

Administer orally in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before

meals. The maximum recommended daily dose is 60 mg. The average dosage is 20 to 30 mg daily. For adult patients who are unable to sleep if medication is taken late in the day, administer the last dose before 6 p.m.

2.3 Dosage Reduction and Discontinuation

If paradoxical aggravation of symptoms or other adverse reactions occur, reduce dosage, or, if necessary, discontinue methylphenidate hydrochloride oral solution. If improvement is not observed after appropriate dosage adjustment over a one-month period, discontinue methylphenidate hydrochloride oral solution.

3 DOSAGE FORMS AND STRENGTHS

Methylphenidate hydrochloride oral solution is a colorless, grape flavored liquid available in a 500 mL bottle in the following strengths:

- 5 mg per 5 mL
- 10 mg per 5 mL

4 CONTRAINDICATIONS

Methylphenidate hydrochloride oral solution is contraindicated in patients:

- with known hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride oral solution. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate *[see Adverse Reactions (6)]*.
- receiving 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)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Methylphenidate hydrochloride oral solution has a high potential for abuse and misuse. The use of methylphenidate hydrochloride exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride, 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 methylphenidate hydrochloride oral solution, 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 methylphenidate hydrochloride oral solution in a safe place, preferably locked, and instruct patients to not give methylphenidate hydrochloride oral solution to anyone else. Throughout methylphenidate hydrochloride 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 methylphenidate hydrochloride use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrythmia, 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 bpm). Some patients may have larger increases.

Monitor all methylphenidate hydrochloride-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 Illness

CNS stimulants may induce a manic or mixed mood episode in patients. Prior to initiating methylphenidate hydrochloride treatment, screen patients for risk factors for developing a 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 dosages, 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 with 0% of placebo-treated patients. If such symptoms occur, consider discontinuing methylphenidate hydrochloride oral solution.

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).

Methylphenidate hydrochloride-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 methylphenidate hydrochloride oral solution, 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 postmarketing reports and at the therapeutic dosages 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 methylphenidate hydrochloride treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for methylphenidate hydrochloride-treated patients who develop signs or symptoms of peripheral vasculopathy.

5.7 Long-Term Suppression of Growth in Pediatric Patients

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

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication-treated pediatric 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 methylphenidate hydrochloride-treated pediatric patients. Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted. The safety and effectiveness of methylphenidate hydrochloride oral solution have not been established in pediatric patient less than 6 years of age.

5.8 Acute Angle Closure Glaucoma

There have been reports of angle closure glaucoma associated with methylphenidate treatment. Although the mechanism is not clear, methylphenidate hydrochloride-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 methylphenidate hydrochloride oral solution to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor methylphenidate hydrochloride-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 methylphenidate hydrochloride oral solution, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor methylphenidate hydrochloride-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

6 ADVERSE REACTIONS

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

- Abuse, misuse, and addiction *[see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)]*
- Known hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride oral solution *[see Contraindications (4)]*
- Hypertensive crisis when used concomitantly with monoamine oxidase inhibitors *[see Contraindications (4), Drug Interactions (7)]*
- 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)]*

The following adverse reactions associated with the use of methylphenidate containing products were identified in clinical studies, postmarketing reports, or literature. Because some of 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.

Infections and infestations: nasopharyngitis

Blood and the lymphatic system disorders: leukopenia, thrombocytopenia, anemia, pancytopenia

Immune system disorders: hypersensitivity reactions, including angioedema and anaphylaxis, auricular swelling, bullous conditions, eruptions, exanthemas

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, affect lability, mania, disorientation, libido changes

Nervous system disorders: headache, dizziness, tremor, dyskinesia including choreoatheetoid movements, drowsiness, convulsions, cerebral arteritis and/or occlusion, serotonin syndrome in combination with serotonergic drugs, migraine, motor and verbal tics

Eye disorders: blurred vision, difficulties in visual accommodation, diplopia, mydriasis, increased intraocular pressure

Cardiac disorders: tachycardia, palpitations, increased blood pressure, arrhythmias, angina pectoris, sudden cardiac death, myocardial infarction, bradycardia, extrasystole

Respiratory, thoracic and mediastinal disorders: cough, pharyngolaryngeal pain, dyspnea

Gastrointestinal disorders: dry mouth, nausea, vomiting, abdominal pain, dyspepsia, diarrhea

General disorders: fatigue, hyperpyrexia

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 angioneurotic edema, erythema, fixed drug eruption

Musculoskeletal and connective tissue disorders: arthralgia, muscle cramps, rhabdomyolysis, myalgia, muscle twitching

Renal and urinary disorders: hematuria

Reproductive system and breast disorders: gynecomastia

Urogenital disorders: priapism

Vascular disorders: peripheral coldness, Raynaud's phenomenon

Investigations: weight loss

7 DRUG INTERACTIONS

7.1 Clinically Important Drug Interactions with Methylphenidate Hydrochloride Oral Solution

Table 1 presents clinically important drug interactions with methylphenidate hydrochloride oral solution.

Table 1: Clinically Important Drug Interactions with Methylphenidate Hydrochloride Oral Solution

Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact:	Concomitant use of MAOIs and CNS stimulants, including methylphenidate hydrochloride oral solution, can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure *[see Contraindications (4)]*.
	Concomitant use of methylphenidate hydrochloride oral solution with

Intervention:	monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuing MAOI treatment is contraindicated.
Antihypertensive Drugs	
Clinical Impact:	Methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution may increase the risk of sudden blood pressure and heart rate increase during surgery.
Intervention:	Avoid use of methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.

Risk Summary

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 use during pregnancy *(see Clinical Considerations)*.

No effects on morphological development were observed in embryo-fetal development studies with oral administration of methylphenidate to pregnant rats and rabbits during organogenesis at doses up to 12 and 19 times, respectively, the maximum recommended human dose (MRHD) of 60 mg/day given to adults on a mg/m^2 basis. However, spina bifida was observed in rabbits at a dose 65 times the MRHD given to adults. A decrease in pup body weight was observed in a pre- and post-natal development study with oral administration of methylphenidate to rats throughout pregnancy and lactation at doses 7 times the MRHD given to adults *(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 methylphenidate hydrochloride oral solution, 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, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Malformations (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 65 times the MRHD of 60 mg/day given to adults on a mg/m^2 basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (19 times the MRHD given to adults on a mg/m^2 basis). There was no evidence of morphological development effects in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (12 times the MRHD of 60 mg/day given to adults on a mg/m^2 basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (4 times the MRHD on a mg/m^2 basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (7 times the MRHD of 60 mg/day given to adults on a mg/m^2 basis), but no other effects on postnatal development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (~2 times the MRHD given to adults on a mg/m^2 basis).

8.2 Lactation

Risk Summary

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 methylphenidate hydrochloride oral solution and any potential adverse effects on the breastfed infant from methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution for the treatment of ADHD have been established in pediatric patients six years of age and older. The safety and effectiveness of methylphenidate hydrochloride oral solution in pediatric patients under six years of age have not been established. The long-term efficacy of methylphenidate in pediatric patients has not been established.

Long-Term Suppression of Growth

Growth should be monitored during treatment with stimulants, including methylphenidate hydrochloride oral solution. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted *[see Warnings and Precautions (5.6)]*.

Juvenile Animal Toxicity Data

In a study conducted in young rats, 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 13-14), 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 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 (5 mg/kg/day) is less than 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

Methylphenidate hydrochloride oral solution has not been studied in the geriatric population.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Methylphenidate hydrochloride oral solution contains methylphenidate hydrochloride, a Schedule II controlled substance.

9.2 Abuse

Methylphenidate hydrochloride oral solution 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)].* Methylphenidate hydrochloride oral solution 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 healthcare

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 methylphenidate hydrochloride oral solution, can result in overdose and death *[see Overdosage (10)],* and this risk is increased with higher doses and or unapproved methods of administration, such as snorting or injection.

9.3 Dependence

Physical Dependence

Methylphenidate hydrochloride oral solution 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 include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Methylphenidate hydrochloride oral solution 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:

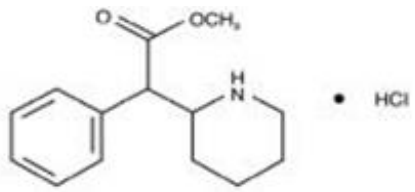
- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin 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. 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

Methylphenidate hydrochloride oral solution is a CNS stimulant available as 5 mg/5 mL and 10 mg/5 mL strengths for oral administration. Chemically, Methylphenidate hydrochloride is (*d,l* racemic) methyl α-phenyl-2-piperidineacetate hydrochloride, and its structural formula is:



Methylphenidate Hydrochloride

$C_{14}H_{19}NO_2 \bullet HCl$ **MW = 269.77**

Methylphenidate hydrochloride, USP is a white, odorless, fine crystalline 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.

Each mL of methylphenidate hydrochloride oral solution 5 mg/5 mL contains 1 mg of methylphenidate hydrochloride, USP.

Each mL of methylphenidate hydrochloride oral solution 10 mg/5 mL contains 2 mg of methylphenidate hydrochloride, USP.

In addition, methylphenidate hydrochloride oral solution also contains the following inactive ingredients: artificial grape flavor, glycerin, hydrochloric acid, polyethylene glycol 1450, and purified water.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Methylphenidate hydrochloride is a central nervous system (CNS) stimulant. The mode of therapeutic action in ADHD is not known.

12.2 Pharmacodynamics

Methylphenidate is a racemic mixture comprised of the *d*- and *l-threo* enantiomers. The *d-threo* enantiomer is more pharmacologically active than the *l-threo* enantiomer. Methylphenidate blocks the reuptake of norepinephrine and dopamine into the presynaptic neuron and increases the release of these monoamines into the extraneuronal space.

Cardiac Electrophysiology

A formal QT study has not been conducted in subjects taking methylphenidate hydrochloride oral solution.

The effect of dexmethylphenidate, the pharmacologically active d-enantiomer of methylphenidate hydrochloride oral solution, on the QT interval was evaluated in a double-blind, placebo- and open-label active (moxifloxacin)-controlled study following single doses of 40 mg dexmethylphenidate hydrochloride extended-release capsule in 75 healthy volunteers. Electrocardiograms were collected up to 12 hours postdose. Frederica's method for heart rate correction was employed to derive the corrected QT interval (QTcF). The maximum mean prolongation of QTcF intervals was less than 5 ms, and the upper limit of the 90% confidence interval was below 10 ms for all time-matched comparisons versus placebo. This was below the threshold of clinical concern and there was no evident exposure response relationship.

12.3 Pharmacokinetics

Absorption

Following a single dose administration of 20 mg methylphenidate hydrochloride oral solution and 20 mg tablet of methylphenidate hydrochloride in healthy volunteers under fasted conditions, time to peak plasma concentration (T_{max}) of methylphenidate was at 1 to 2 hours after dosing, and:

- The mean peak plasma concentration (C_{max}) of methylphenidate was 9.1 ng/mL and 9.8 ng/mL, respectively.
- The mean area under concentration curve (AUC) of methylphenidate was 46.7 hour*ng/mL and 50.0 hour*ng/mL, respectively.

Effect of Food

Ingestion of a high-fat meal with methylphenidate hydrochloride oral solution increased methylphenidate mean C_{max} and AUC by about 13% and 25%, respectively. Time to C_{max} (T_{max}) was delayed by approximately 1 hour.

Distribution

Plasma protein binding is 10% to 33%. The volume of distribution was 2.65 ± 1.11 L/kg for d-methylphenidate and 1.80 ± 0.91 L/kg for l-methylphenidate.

Elimination

The mean terminal half-life (t1/2) of methylphenidate was 2.7 hours following administration of 20 mg methylphenidate hydrochloride oral solution. The systemic clearance is 0.40 ± 0.12 L/h/kg for d-methylphenidate and 0.73 ± 0.28 L/h/kg for l-methylphenidate.

Metabolism

Methylphenidate is metabolized primarily by deesterification to alpha-phenyl-piperidine acetic acid (ritalinic acid), which has little or no pharmacologic activity.

Excretion

After oral dosing of radiolabeled methylphenidate in humans, about 90% of the radioactivity was recovered in urine. The main urinary metabolite was ritalinic acid,

accounting for approximately 80% of the dose.

Specific Populations

Male and Female Patients, Racial Groups, and Age

The effect of gender, race, and age on the pharmacokinetics of methylphenidate after methylphenidate hydrochloride oral solution administration have not been studied.

Patients with Renal Impairment

Methylphenidate hydrochloride oral solution has not been studied in patients with renal impairment. Since renal clearance is not an important route of methylphenidate clearance, renal impairment is expected to have little effect on the pharmacokinetics of methylphenidate hydrochloride oral solution.

Patients with Hepatic Impairment

Methylphenidate hydrochloride oral solution has not been studied in patients with hepatic impairment. Since methylphenidate is metabolized primarily to ritalinic acid by nonmicrosomal hydrolytic esterases that are widely distributed throughout the body, hepatic impairment is expected to have minimal effect on the pharmacokinetics of methylphenidate hydrochloride oral solution.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 5 times the maximum recommended human dose (MRHD) of 60 mg/kg given to adults 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.

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 7 times the MRHD (adults) on a mg/m^2 basis.

In a 24-week carcinogenicity study 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 concentration of methylphenidate as in the lifetime carcinogenicity study; the high-dose groups were exposed to 60 to 74 mg/kg/day of methylphenidate.

Mutagenesis

Methylphenidate 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 vitro* chromosomal aberration assay using human lymphocytes. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in

an *in vitro* assay in cultured Chinese Hamster Ovary (CHO) cells. Methylphenidate was negative *in vivo* in males and females in the mouse bone marrow micronucleus assay.

Impairment of Fertility

No human data on the effect of methylphenidate on fertility are available. 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 up to 160 mg/kg/day, approximately 13 times the maximum recommended human dose of 60 mg/day given to adults on a mg/m^2 basis.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Methylphenidate hydrochloride oral solution 10 mg per 5 mL is a colorless grape flavored liquid. It is supplied in bottles of 500 mL, NDC 72162-2041-5.

Storage and Handling

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Dispense in tight container with child-resistant closure.

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

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 methylphenidate hydrochloride oral solution, 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 methylphenidate hydrochloride oral solution in a safe place, preferably locked, and instruct patients to not give methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution 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 methylphenidate hydrochloride oral solution can elevate blood pressure and heart rate *[see Warnings and Precautions (5.3)]*.

Psychiatric Adverse Reactions

Advise patients that methylphenidate hydrochloride oral solution, 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 the patient 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 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 methylphenidate hydrochloride oral solution. 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 methylphenidate hydrochloride oral solution may cause slowing of growth and weight loss in pediatric patients *[see Warnings and Precautions (5.7)]*.

Increased Intraocular Pressure (IOP) and Glaucoma

Advise patients that IOP and glaucoma may occur during treatment with methylphenidate hydrochloride oral solution *[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 methylphenidate hydrochloride oral solution. 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 Exposure Registry

Inform patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in patients exposed to methylphenidate hydrochloride oral solution during pregnancy *[see Use in Specific Populations (8.1)]*.

Manufactured by:

Tris Pharma Inc.

Monmouth Junction, NJ 08852

www.trispharma.com

LB8477

Rev. 03

12/2023

MEDICATION GUIDE

Methylphenidate Hydrochloride Oral Solution CII
(METH il FEN i date)
5 mg/5 mL and 10 mg/5 mL
Rx only

What is the most important information I should know about Methylphenidate Hydrochloride Oral Solution?
Methylphenidate Hydrochloride Oral Solution may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Methylphenidate Hydrochloride Oral Solution has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of Methylphenidate Hydrochloride Oral Solution, 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 Methylphenidate Hydrochloride Oral Solution 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 Methylphenidate Hydrochloride Oral Solution and will monitor you or your child during treatment.
  - Methylphenidate Hydrochloride Oral Solution may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give Methylphenidate Hydrochloride Oral Solution to anyone else. See **"What is Methylphenidate Hydrochloride Oral Solution?"** for more information.
  - Keep Methylphenidate Hydrochloride Oral Solution in a safe place and properly dispose of any unused medicine. See **"How should I store Methylphenidate Hydrochloride Oral Solution?"** 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 treatment with Methylphenidate Hydrochloride Oral Solution. 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 have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with Methylphenidate Hydrochloride Oral Solution.
- **Increased blood pressure and heart rate.**
  Your healthcare provider should check your or your child's blood pressure and heart rate regularly during treatment with Methylphenidate Hydrochloride Oral Solution.
- **Mental (psychiatric) problems, including:**

  - new or worse behavior and thought problems
  - new or worse bipolar illness

- new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) 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 during treatment with Methylphenidate Hydrochloride Oral Solution, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is Methylphenidate Hydrochloride Oral Solution?

Methylphenidate Hydrochloride Oral Solution is a prescription medicine used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. Methylphenidate Hydrochloride Oral Solution may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.

It is not known if Methylphenidate Hydrochloride Oral Solution is safe and effective for use in children under 6 years of age.

Methylphenidate Hydrochloride Oral Solution is a federally controlled substance (CII) because it contains methylphenidate that can be a target for people who abuse prescription medicines or street drugs.

Keep Methylphenidate Hydrochloride Oral Solution in a safe place to protect it from theft. Never give your Methylphenidate Hydrochloride Oral Solution to anyone else, because it may cause death or harm them. Selling or giving away Methylphenidate Hydrochloride Oral Solution may harm others and is against the law.

Do not take Methylphenidate Hydrochloride Oral Solution if you or your child are:

- allergic to methylphenidate hydrochloride or any of the ingredients in Methylphenidate Hydrochloride Oral Solution. See the end of this Medication Guide for a complete list of ingredients in Methylphenidate Hydrochloride Oral Solution.
- taking, or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).

Before taking Methylphenidate Hydrochloride Oral Solution tell your healthcare provider about all your medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure
- have mental problems including psychosis, mania, bipolar illness, or depression, or have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and 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
- are pregnant or plan to become pregnant. It is not known if Methylphenidate Hydrochloride Oral Solution will harm the unborn baby.
  - There is a pregnancy registry for females who are exposed to Methylphenidate Hydrochloride Oral Solution during pregnancy. The purpose of the registry is to collect information about the health of females exposed to Methylphenidate Hydrochloride Oral Solution and their baby. If you or your child becomes pregnant

during treatment with Methylphenidate Hydrochloride Oral Solution, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388.

- are breastfeeding or plan to breastfeed. Methylphenidate Hydrochloride Oral Solution passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with Methylphenidate Hydrochloride Oral Solution.

Tell your healthcare provider about all the medicines that you take or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Methylphenidate Hydrochloride Oral Solution 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 Methylphenidate Hydrochloride Oral Solution. Your healthcare provider will decide whether Methylphenidate Hydrochloride Oral Solution can be taken with other medicines.
Especially tell your healthcare provider if you or your child take a medicine used to treat depression called a monoamine oxidase inhibitor (MAOI).
Know the medicines that you take or your child take. Keep a list of your medicines with you to show your healthcare provider and pharmacist. **Do not start any new medicine during treatment with Methylphenidate Hydrochloride Oral Solution without talking to your healthcare provider first.**

How should Methylphenidate Hydrochloride Oral Solution be taken?

- Take Methylphenidate Hydrochloride Oral Solution exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.

- **Children 6 years of age and older:**

  - Take Methylphenidate Hydrochloride Oral Solution by mouth 2 times a day before breakfast and lunch, 30 to 45 minutes before a meal, as prescribed by your healthcare provider.

- **Adults:**
  - Take Methylphenidate Hydrochloride Oral Solution by mouth 2 or 3 times a day, 30 to 45 minutes before a meal, as prescribed by your healthcare provider.
  - For adults who have sleep problems when Methylphenidate Hydrochloride Oral Solution is taken late in the day, take your last dose of Methylphenidate Hydrochloride Oral Solution before 6 p.m.

- If you or your child take too much Methylphenidate Hydrochloride Oral Solution, 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 Methylphenidate Hydrochloride Oral Solution?
Methylphenidate Hydrochloride Oral Solution may cause serious side effects, including:

- See **"What is the most important information I should know about Methylphenidate Hydrochloride Oral Solution?**"
- **Painful and prolonged erections (priapism).** Priapism has happened in males

who take products that contain methylphenidate. **If you or your child develop priapism, get medical help right away.**

- **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 healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes, or if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with Methylphenidate Hydrochloride Oral Solution.
- **Slowing of growth (height and weight) in children**. Children should have their height and weight checked often during treatment with Methylphenidate Hydrochloride Oral Solution. Methylphenidate Hydrochloride Oral Solution 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 Methylphenidate Hydrochloride Oral Solution.

The most common side effects of Methylphenidate Hydrochloride Oral Solution include:

• increased heart rate • headache • anxiety • weight loss • dry mouth • stomach pain	• irregular heart beat (palpitations) • trouble sleeping • sweating • decreased appetite • nausea

These are not all the possible side effects of Methylphenidate Hydrochloride Oral Solution.
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 Methylphenidate Hydrochloride Oral Solution?

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

Keep Methylphenidate Hydrochloride Oral Solution and all medicines out of the reach of children.

General information about the safe and effective use of Methylphenidate Hydrochloride Oral Solution.

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

What are the ingredients in Methylphenidate Hydrochloride Oral Solution?

Active Ingredient: methylphenidate hydrochloride, USP

Inactive Ingredients: artificial grape flavor, glycerin, hydrochloric acid, polyethylene glycol 1450, and purified water.

Manufactured by:

Tris Pharma, Inc.

Monmouth Junction, NJ 08852

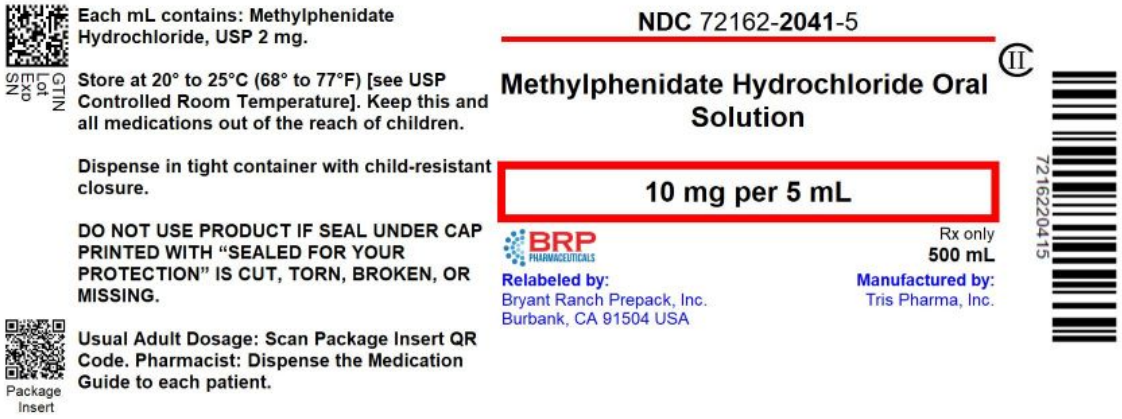
For more information about Methylphenidate Hydrochloride Oral Solution contact Tris Pharma, Inc at 732-940-0358 or go to www.trispharma.com.

LB8478

Rev. 03

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised: 12/2023

Methylphenidate Hydrochloride Oral Solution (CII) 10 mg/5 mL



METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72162-2041(NDC:27808-059)
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI) (METHYLPHENIDATE - UNII:207ZZ9QZ49)	METHYLPHENIDATE HYDROCHLORIDE	10 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
WATER (UNII: 059QF0KO0R)	
GRAPE (UNII: 6X543N684K)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72162-2041-5	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/03/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091601	03/04/2015	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2041) , RELABEL(72162-2041)