

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use METHYLPHENIDATE HYDROCHLORIDE tablets safely and effectively. See full prescribing information for METHYLPHENIDATE HYDROCHLORIDE TABLETS.

METHYLPHENIDATE HYDROCHLORIDE tablets, for oral use, CII
Initial U.S. Approval: 1955

WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

Methylphenidate hydrochloride tablets 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 tablets, can result in overdose and death (5.1, 9.2, 10);

• Before prescribing methylphenidate hydrochloride tablets, 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.

INDICATIONS AND USAGE

Methylphenidate hydrochloride is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorders (ADHD) and Narcolepsy (1).

DOSAGE AND ADMINISTRATION

- Pediatric Patients 6 Years and Older: Start with 5 mg twice daily (before breakfast and lunch), titrating the dose weekly in 5- to 10-mg increments. Dosages above 60 mg/day are not recommended (2,2).
- Adults: Average daily dosage is 20 mg to 30 mg, administered 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum total daily dosage is 60 mg (2,2).

DOSAGE FORMS AND STRENGTHS

- Tablets: 5 mg, 10 mg, and 20 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to methylphenidate or other product components of methylphenidate hydrochloride tablets (4).

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FULL PRESCRIBING INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

Methylphenidate hydrochloride tablets 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 tablets, 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 tablets, 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 tablets 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 tablets are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorders (ADHD) in pediatric patients 6 years and older and adults
- Narcolepsy

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating patients with methylphenidate hydrochloride tablets, assess:

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

2.2 General Dosing Information

Pediatric Patients 6 Years and Older: Start with 5 mg orally twice daily (before breakfast and lunch). Increase dosage gradually, in increments of 5- to 10-mg weekly. Daily dosage above 60 mg is not recommended.

Adults: Average dosage is 20 to 30 mg daily. Administer orally in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum total daily dosage is 60 mg. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

2.3 Dosage Reduction and Discontinuation

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

3 DOSAGE FORMS AND STRENGTHS

Tablets

- 5 mg, Light yellow, round, biconvex, beveled edge tablets de-bossed with "T" on one side and '173' on the other side.
- 10 mg, White to off white, round, flat, beveled edge tablets de-bossed with "T" and '174' with a break line on one side and plain on the other side.
- 20 mg, Light yellow, round, flat, beveled edge tablets de-bossed with "T" and '175' with a break line on one side and plain on the other side.

4 CONTRAINDICATIONS

- Hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride tablets. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported in patients treated with methylphenidate [see Adverse Reactions (6)].
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of treatment with an MAOI, because of the risk of hypertensive crises [see Drug Interactions (7.1)].

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Methylphenidate hydrochloride have 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 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 tablets, 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 tablets, 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 tablets in a safe place, preferably locked, and instruct patients to not give methylphenidate hydrochloride tablets to anyone else. Throughout methylphenidate hydrochloride tablets 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 are treated with CNS stimulants at the recommended ADHD dosage.

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

5.3 Increased Blood Pressure and Heart Rate

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

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed mood episode in patients. Prior to initiating 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 dosage, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients, compared to 0% of placebo-treated patients. If such symptoms occur, consider discontinuing methylphenidate hydrochloride.

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.

- 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 tablets, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing methylphenidate hydrochloride tablets (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 tablets treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5.6).
 - **Long-Term Suppression of Growth in Pediatric Patients:** Closely monitor growth (height and weight) in pediatric patients. Pediatric patients not growing or gaining height or weight as expected may need to have their treatment interrupted (5.7).
 - **Acute Angle Closure Glaucoma:** Methylphenidate hydrochloride tablets-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 tablets 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 tablets, 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 Camber Pharmaceuticals Inc., at 1-866-495-8330 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.

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5.6 Peripheral Vasculopathy, Including Raynaud's Phenomenon

CNS stimulants, including methylphenidate hydrochloride, 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 dosage of CNS stimulants in all age groups throughout the course of treatment. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant.

Careful observation for digital changes is necessary during 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.

Controlled follow-up of weight and height in pediatric patients aged 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated patients over 36 months (to the ages of 10 to 13 years), suggests that pediatric patients who received methylphenidate for 7 days per week throughout the year had a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.1 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-treated pediatric patients. Pediatric patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

5.8 Acute Angle Closure Glaucoma

There have been reports of angle closure glaucoma associated with methylphenidate treatment.

Although the mechanism is not clear, 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)].

Prescribe methylphenidate hydrochloride 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)].

Before initiating methylphenidate hydrochloride, 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 are discussed in more detail in other sections of the labeling:

- Abuse, Misuse, and Addiction [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)]
- Known hypersensitivity to methylphenidate or other ingredients of methylphenidate hydrochloride tablets [see Contraindications (4)]
- Hypertensive crises with Concomitant Use of Monoamine Oxidase Inhibitors [see Contraindications (4), Drug Interactions (7.1)]
- Risks to Patients with Serious Cardiac Disease [see Warnings and Precautions (5.2)]
- Increased Blood Pressure and Heart Rate [see Warnings and Precautions (5.3)]
- Psychiatric Adverse Reactions [see Warnings and Precautions (5.4)]
- Priapism [see Warnings and Precautions (5.5)]
- Peripheral Vasculopathy, Including Raynaud's Phenomenon [see Warnings and Precautions (5.6)]
- Long-Term Suppression of Growth in Pediatric Patients [see Warnings and Precautions (5.7)]
- Acute Angle Closure Glaucoma [see Warnings and Precautions (5.8)]
- Increased Intraocular Pressure and Glaucoma [see Warnings and Precautions (5.9)]
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome [see Warnings and Precautions (5.10)]

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

Adverse Reactions Reported with Methylphenidate Hydrochloride

Infections and Infestations: nasopharyngitis

Blood and Lymphatic System Disorders: leukopenia, thrombocytopenia, anemia

Immune System Disorders: hypersensitivity reactions, including angioedema, and anaphylaxis

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

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

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

Eye Disorders: blurred vision, difficulties in visual accommodation

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

Respiratory, Thoracic, and Mediastinal Disorders: cough

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

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

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

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

Investigations: weight loss (adult ADHD patients)

Vascular Disorders: peripheral coldness, Raynaud's phenomenon

Additional Adverse Reactions Reported with Other Methylphenidate-Containing Products

The list below shows adverse reactions not listed for methylphenidate hydrochloride that have been reported with other methylphenidate-containing products.

Blood and Lymphatic Disorders: pancytopenia

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

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

Nervous System Disorders: migraine, motor and verbal tics

Eye Disorders: diplopia, increased intraocular pressure, mydriasis

Cardiac Disorders: sudden cardiac death, myocardial infarction, bradycardia, extrasystole

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

Gastrointestinal Disorders: diarrhea, constipation

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

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

Renal and Urinary Disorders: hematuria

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Methylphenidate Hydrochloride tablets

USP
Ascent
tablets

Reproductive System and Breast Disorders: gynecomastia

General Disorders: fatigue, hyperpyrexia

Urogenital Disorders: priapism

7 DRUG INTERACTIONS

7.1 Clinically Important Drug Interactions with Methylphenidate Hydrochloride

Table 1 presents clinically important drug interactions with methylphenidate hydrochloride tablets

Table 1: Clinically Important Drug Interactions with Methylphenidate Hydrochloride

Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact	Concomitant use of MAOIs and CNS stimulants, including methylphenidate hydrochloride can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure [see Contraindications (4)].
Intervention	Concomitant use of methylphenidate hydrochloride with MAOIs or within 14 days after discontinuing MAOI treatment is contraindicated.
Antihypertensive Drugs	
Clinical Impact	Methylphenidate hydrochloride 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 may increase the risk of sudden blood pressure and heart rate increase during surgery.
Intervention	Avoid use of methylphenidate hydrochloride 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 tablets, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visiting <https://womensmentalhealth.org/adhd-medications/>.

Risk Summary

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 10 and 15 times, respectively, the maximum recommended human dose (MRHD) of 60 mg/day given to adolescents on a mg/m² basis. However, spina bifida was observed in rabbits at a dose 52 times the MRHD given to adolescents. 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 6 times the MRHD given to adolescents [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 tablets, 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 52 times the MRHD of 60 mg/day given to adolescents on a mg/m² basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (15 times the MRHD given to adolescents on a mg/m² 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 (10 times the MRHD of 60 mg/day given to adolescents on a mg/m² basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (3 times the MRHD on a mg/m² 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 (6 times the MRHD of 60 mg/day given to adolescents on a mg/m² 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 (approximately 2 times the MRHD given to adolescents on a mg/m² 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 and any potential adverse effects on the breastfed infant from methylphenidate hydrochloride or from the underlying maternal condition.

Clinical Considerations

Monitor breastfed infants for adverse reactions, such as

Advise patients that IOP and glaucoma may occur during treatment with methylphenidate hydrochloride tablets [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 tablets. Instruct patients to notify their healthcare provider if emergence of new tics or worsening of tics or Tourette's syndrome occurs [see Warnings and Precautions (5.10)].

Pregnancy Registry

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

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MEDICATION GUIDE
Methylphenidate hydrochloride tablets, USP
(meth" il fen' i date hye" droe klor' ide)

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

- **Abuse, misuse, and addiction.** Methylphenidate hydrochloride has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of methylphenidate hydrochloride, 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 tablets 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 tablets and will monitor you or your child during treatment.
 - Methylphenidate hydrochloride tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give methylphenidate hydrochloride tablets to anyone else. See **"What are methylphenidate hydrochloride tablets?"** for more information.
 - Keep methylphenidate hydrochloride tablets in a safe place and properly dispose of any unused medicine. See **"How should I store methylphenidate hydrochloride tablets?"** 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 methylphenidate hydrochloride tablets. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.

Call your healthcare provider or go to the nearest hospital emergency room right away if you or your child has any signs of heart problems, such as chest pain, shortness of breath, or fainting while taking methylphenidate hydrochloride tablets.

- **Increased blood pressure and heart rate.**

Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride tablets.

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

Tell your healthcare provider about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems while taking methylphenidate hydrochloride tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are methylphenidate hydrochloride tablets?

- Methylphenidate hydrochloride tablets are a central nervous system (CNS) stimulant prescription medicine. **It is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** Methylphenidate hydrochloride tablets may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.
- Methylphenidate hydrochloride tablets should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.
- Methylphenidate hydrochloride tablets are also used in the treatment of a sleep disorder called narcolepsy.

It is not known if methylphenidate hydrochloride tablets are safe and effective in children under 6 years of age.

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

Who should not take methylphenidate hydrochloride tablets?

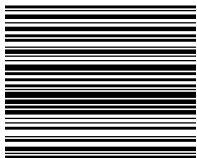
Methylphenidate hydrochloride tablets should not be taken if you or your child:

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

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

- heart problems, heart disease, heart defects, or high blood pressure
- mental problems, including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or toes
- have eye problems, including increased pressure in your eye, glaucoma, or problems with your close-up vision (farsightedness)
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome.
- if you are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride tablets will harm your unborn baby.

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Methylphenidate
hydrochloride
tablets

- There is a pregnancy registry for females who are exposed to ADHD medications, including methylphenidate hydrochloride, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to methylphenidate hydrochloride and their baby. If you or your child becomes pregnant during treatment with methylphenidate hydrochloride, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhd-medications/>.

- if you are breastfeeding or plan to breastfeed. Methylphenidate hydrochloride passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with methylphenidate hydrochloride.

Tell your healthcare provider about all of the medicines that you or your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Methylphenidate 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 adjusted while taking methylphenidate hydrochloride tablets.

Your healthcare provider will decide whether methylphenidate hydrochloride tablets can be taken with other medicines.

Especially tell your healthcare provider if you or your child takes:

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

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

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

Do not start any new medicine while taking methylphenidate hydrochloride tablets without talking to your healthcare provider first.

How should methylphenidate hydrochloride tablets be taken?

- Take methylphenidate hydrochloride tablets exactly as prescribed. Your healthcare provider may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride tablets is usually taken 2 to 3 times a day.
- Take methylphenidate hydrochloride tablets 30 to 45 minutes before a meal.
- Your healthcare provider may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride tablets. Children should have their height and weight checked often while taking methylphenidate hydrochloride tablets. If you or your child take too much methylphenidate hydrochloride tablets, 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 tablets?

Methylphenidate hydrochloride tablets may cause serious side effects, including:

- see **"What is the most important information I should know about methylphenidate hydrochloride tablets?"** for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a healthcare provider immediately.
- **circulation problems in fingers and toes** (peripheral vasculopathy, including Raynaud's phenomenon):
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change color from pale, to blue, to redTell your healthcare provider if you or your child have, numbness, pain, skin color change, or sensitivity to temperature in the fingers or toes.

Call your healthcare provider right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking methylphenidate hydrochloride tablets.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride tablets. Methylphenidate hydrochloride tablets 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 tablets.

Common side effects include:

- fast heart beat
- abnormal heartbeat (palpitations)
- sweating a lot
- decreased appetite
- headache
- trouble sleeping
- nausea
- stomach pain
- nervousness

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 tablets?

- Store methylphenidate hydrochloride tablets in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.

- Dispose of remaining, unused, or expired methylphenidate 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 methylphenidate 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 methylphenidate hydrochloride tablets in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

- **Keep methylphenidate hydrochloride tablets and all medicines out of the reach of children.**

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

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

What are the ingredients in methylphenidate hydrochloride tablets?

Active Ingredient: methylphenidate HCl.

Inactive Ingredients: Methylphenidate hydrochloride tablets, USP

contain inactive ingredients: compressible sugar, colloidal silicon dioxide, D&C yellow no. 10 (5 mg and 20 mg tablets), lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

Manufactured by:
Ascent Pharmaceuticals, Inc.
Central Islip, NY 11722.

Manufactured for:
Camber Pharmaceuticals, Inc.
Piscataway, NJ 08854.

For more information and request for additional copies of the Medication Guide, call Camber Pharmaceuticals Inc., at 1-866-495-8330.

Medication Guide available at <http://camberpharma.com/medication-guides>

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

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