928-09-2026

METHYLPHENIDATE HYDROCHLORIDE CHEWABLE TABLETS CII

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

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

**METHYLPHENIDATE HYDROCHLORIDE chewable 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 chewable 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 chewable tablets, can result in overdose and death (5.1, 9.2, 10):**

- **Before prescribing methylphenidate hydrochloride chewable 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.**

**----------RECENT MAJOR CHANGES----------**

Contraindications (4) XX/XXXX

**----------INDICATIONS AND USAGE----------**

Methylphenidate hydrochloride chewable tablets are a central nervous system (CNS) stimulant indicated for the treatment of:

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

**----------DOSAGE AND ADMINISTRATION----------**

- Pediatric Patients 6 Years and Older: Start with 5 mg twice daily (before breakfast and lunch); titrate the dose in weekly increments of 5 mg to 10 mg. Daily dosages above 60 mg are not recommended. (2.2)
- Adults: Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum recommended daily dosage is 60 mg. (2.2)
- Administer with at least 8 ounces (a full glass) of water or other fluid. (2.2)

**----------DOSAGE FORMS AND STRENGTHS----------**

Chewable tablets: 2.5 mg, 5 mg, and 10 mg. (3)

**----------CONTRAINDICATIONS----------**

Methylphenidate hydrochloride chewable tablets are contraindicated in:

- Known hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride chewable tablets (4)
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days (4)
- Patients with pheochromocytoma or a history of pheochromocytoma (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 chewable tablets, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing methylphenidate hydrochloride chewable 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 chewable 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 chewable 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 chewable 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 chewable 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)
- Risk of Choking: Taking this product without enough liquid may cause choking. Discontinue methylphenidate hydrochloride chewable tablets and seek immediate medical attention if chest pain, vomiting, difficulty in swallowing, or difficulty in breathing occur after administration. (5.11)
- Risks in Patients with Phenylketonuria: Methylphenidate hydrochloride chewable tablets contains phenylalanine which can be harmful to patients with phenylketonuria. (5.12)

**----------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.**

**Revised: 09/2026**

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**FULL PRESCRIBING INFORMATION**

**WARNING: ABUSE, MISUSE, AND ADDICTION**

**Methylphenidate hydrochloride chewable 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 chewable 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 chewable 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 chewable 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 chewable tablets are indicated for the treatment of:

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

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Pretreatment Screening

Prior to treating patients with methylphenidate hydrochloride chewable 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 chewable tablets *[see Warnings and Precautions (5.10)]*.

### 2.2 Recommended Dosage and Administration Information

Pediatric Patients 6 years 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 dosage is 60 mg daily. 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.

Administer methylphenidate hydrochloride chewable tablets with at least 8 ounces (a full glass) of water or other fluid. Do not swallow whole. Taking this product without enough liquid may cause choking *[see Warnings and Precautions (5.11)]*.

### 2.3 Dosage Reduction and Discontinuation

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

## 3 DOSAGE FORMS AND STRENGTHS

Chewable tablets:

- 2.5 mg of methylphenidate hydrochloride chewable tablet is available as a white to off-white round beveled edge chewable tablets debossed with **'260'** on one side and **'AT'** on the other side.
- 5 mg of methylphenidate hydrochloride chewable tablet is available as a white to off-white round beveled edge chewable tablets debossed with **'261'** on one side and **'AT'** on the other side.
- 10 mg of methylphenidate hydrochloride chewable tablet is available as a white to off-white flat round chewable tablets debossed with **'AT'** on left side and **'262'** on the right side of the bisect line and other side plain.

## 4 CONTRAINDICATIONS

Methylphenidate hydrochloride chewable tablets are contraindicated in patients:

- with a known hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride chewable tablets. 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), and also within 14 days following discontinuation of treatment with a MAOI, because of the risk of hypertensive crisis *[see Drug Interactions (7.1)]*.

Patients with pheochromocytoma or a history of pheochromocytoma. Serious reactions, including elevated blood pressure and tachyarrhythmia, have been reported in patients with pheochromocytoma or a history of pheochromocytoma who received an amphetamine product.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Abuse, Misuse, and Addiction

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

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

### 5.3 Increased Blood Pressure and Heart Rate

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

Monitor all methylphenidate hydrochloride chewable tablets-treated patients for hypertension and tachycardia.

### 5.4 Psychiatric Adverse Reactions

Exacerbation of Pre-Existing Psychosis

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

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating methylphenidate hydrochloride chewable tablets 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, and 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 chewable tablets.

### 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 a methylphenidate withdrawal (drug holidays or during discontinuation).

Methylphenidate hydrochloride chewable tablets-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, such as methylphenidate hydrochloride chewable tablets, 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 reduction or discontinuation of the CNS stimulant.

Careful observation for digital changes is necessary during methylphenidate hydrochloride chewable tablets treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for methylphenidate hydrochloride chewable tablets-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 pediatric patients ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated 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 chewable tablets-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 chewable tablets-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 chewable 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 methylphenidate hydrochloride chewable tablets-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 chewable tablets, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor methylphenidate hydrochloride chewable tablets-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

### 5.11 Risk of Choking

Methylphenidate hydrochloride chewable tablets may swell and block the throat or esophagus which can cause the patient to choke. Avoid use of methylphenidate hydrochloride chewable tablets in patients who have difficulty swallowing. Administer with at least 8 ounces of fluid *[see Dosage and Administration (2.2)]*. Discontinue methylphenidate hydrochloride chewable tablets and seek immediate medical attention if chest pain, vomiting, difficulty in swallowing, or difficulty in breathing occur after administration.

### 5.12 Risks in Patients with Phenylketonuria

Phenylalanine can be harmful to patients with phenylketonuria (PKU). Methylphenidate hydrochloride chewable tablets contain phenylalanine, a component of aspartame. Each 2.5 mg methylphenidate hydrochloride chewable tablet contains 0.35 mg of phenylalanine; each 5 mg methylphenidate hydrochloride chewable tablet contains 0.70 mg of phenylalanine and each 10 mg methylphenidate hydrochloride chewable tablet contains 1.40 mg of phenylalanine. Before prescribing methylphenidate hydrochloride chewable tablets to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including methylphenidate hydrochloride chewable tablets.

## 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 chewable tablets *[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)]*
- Risk of Choking *[see Warnings and Precautions (5.11)]*
- Risks in Patients with Phenylketonuria *[see Warnings and Precautions (5.12)]*

The following adverse reactions associated with the use of methylphenidate containing products were identified in other 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 choreoathetoid 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

Table 1 presents clinically important drug interactions with methylphenidate hydrochloride chewable tablets.

**Table 1: Drugs Having Clinically Important Interactions with Methylphenidate Hydrochloride Chewable Tablets**

| | |
|---|---|
| Monoamine Oxidase Inhibitors (MAOI) | |
| *Clinical Impact:* | Concomitant use of MAOIs and CNS stimulants, including methylphenidate hydrochloride chewable tablets, 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 chewable tablets with monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuing MAOI treatment is contraindicated. |
| Antihypertensive Drugs | |
| *Clinical Impact:* | Methylphenidate hydrochloride chewable tablets 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 chewable tablets may increase the risk of sudden blood pressure and heart rate increase during surgery. |
| *Intervention:* | Avoid use of methylphenidate hydrochloride chewable tablets 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, during pregnancy. Healthcare providers are encouraged to advise patients to register by calling the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visiting online at www.womensmentalhealth.org/research/pregnancyregistry/adhd-medications/.

Risk Summary

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 chewable 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 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 (approximately 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 chewable tablets and any potential adverse effects on the breastfed infant from methylphenidate hydrochloride chewable tablets 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 chewable tablets for the treatment of ADHD have been established in pediatric patients six years of age and older. The safety and effectiveness of methylphenidate hydrochloride chewable tablets 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 chewable tablets. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted *[see Warnings and Precautions (5.7), Adverse Reactions (6.1)]*.

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 to 14), decreased spontaneous locomotor activity was observed in males and females previously treated with 50 mg/kg/day (approximately 4 times the MRHD of 60 mg/day 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 has not been studied in the geriatric population.

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**8.6 Renal Impairment**

Methylphenidate hydrochloride has not been studied in patients with renal impairment.

**9 DRUG ABUSE AND DEPENDENCE**

**9.1 Controlled Substance**

Methylphenidate hydrochloride chewable tablets contains methylphenidate, a Schedule II controlled substance.

**9.2 Abuse**

Methylphenidate hydrochloride chewable tablets 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 chewable tablets 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 chewable 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.

**9.3 Dependence**

Physical Dependence

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

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

Tolerance

Methylphenidate hydrochloride chewable tablets 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.

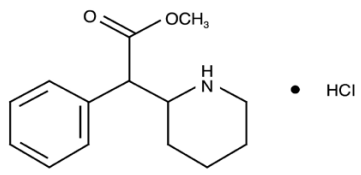
Posterior reversible encephalopathy syndrome (PRES) symptoms including headache, altered mental status, hypertension, seizures, and visual disturbances including blindness have occurred in the setting of an amphetamine product overdose. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Diagnosis of PRES should be confirmed by radiological procedure (e.g., MRI).

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 chewable tablets contain methylphenidate, a CNS stimulant, in the hydrochloride salt form. The chemical name of methylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride. The molecular weight is 269.77. Its molecular formula is $C_{14}H_{19}NO_2$ • HCl, and it has the following chemical structure.




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.

Methylphenidate hydrochloride chewable tablets are for oral administration, and each tablet contains 2.5 mg, 5 mg or 10 mg of methylphenidate hydrochloride USP (equivalent to 2.2 mg, 4.3 mg, or 8.6 mg of methylphenidate respectively).

Methylphenidate hydrochloride chewable tablets contain the following inactive ingredients: aspartame, lactose anhydrous, microcrystalline cellulose, guar gum, grape flavor, pregelatinized starch, and stearic acid.

**12 CLINICAL PHARMACOLOGY**

**12.1 Mechanism of Action**

Methylphenidate hydrochloride is a central nervous system (CNS) stimulant. The mode of therapeutic action in ADHD and narcolepsy 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 chewable tablets.

The effect of dexmethylphenidate, the pharmacologically active d-enantiomer of methylphenidate hydrochloride, 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 oral administration of methylphenidate hydrochloride chewable tablets, peak plasma methylphenidate concentrations are achieved at about 1 to 2 hours. The mean $C_{max}$ following a 20 mg dose is approximately 10 ng/mL.

No clinically significant difference in methylphenidate pharmacokinetics was observed between methylphenidate hydrochloride chewable tablets and immediate-release methylphenidate hydrochloride tablet.

*Effect of Food*

In a study in adult volunteers investigating the effects of a high-fat meal on the bioavailability of methylphenidate hydrochloride chewable tablets at a dose of 20 mg, the presence of food delayed the peak concentrations by approximately 1 hour (1.5 hours, fasted and 2.4 hours, fed). Overall, a high-fat meal increased the AUC of methylphenidate hydrochloride chewable tablets by about 20%, on average.

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 ($t_{½}$) of methylphenidate was 3 hours following administration of 20 mg methylphenidate hydrochloride chewable tablet. 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*

In humans, methylphenidate is metabolized primarily via deesterification to alpha-phenylpiperidine acetic acid (PPA, ritalinic acid). The metabolite 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 PPA, accounting for approximately 80% of the dose.

The pharmacokinetics of the methylphenidate hydrochloride chewable tablets have been studied in healthy adult volunteers. The mean terminal half-life ($t_{½}$) of methylphenidate following administration of 20 mg methylphenidate hydrochloride chewable tablets is 3 hours.

*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 chewable tablets administration have not been studied.

*Patients with Renal Impairment*

There is no experience with the use of methylphenidate hydrochloride chewable tablets in patients with renal insufficiency. After oral administration of radiolabeled methylphenidate in humans, methylphenidate was extensively metabolized and approximately 80% of the radioactivity was excreted in the urine in the form of ritalinic acid. Since renal clearance is not an important route of methylphenidate clearance, renal insufficiency is expected to have little effect on the pharmacokinetics of methylphenidate hydrochloride chewable tablets.

*Patients with Hepatic Impairment*

There is no experience with the use of methylphenidate hydrochloride chewable tablets in patients with hepatic insufficiency.

**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) 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

Each methylphenidate hydrochloride chewable tablet 2.5 mg is available as a white to off-white round beveled edge chewable tablets debossed with **'260'** on one side and **'AT'** on the other side.

Bottles of 100 NDC 31722-926-01

Each methylphenidate hydrochloride chewable tablet 5 mg is available as a white to off-white round beveled edge chewable tablets debossed with **'261'** on one side and **'AT'** on the other side.

Bottles of 100 NDC 31722-927-01

Each methylphenidate hydrochloride chewable tablet 10 mg is available as a white to off-white flat round chewable tablets debossed with **'AT'** on left side and **'262'** on the right side of the bisect line and other side plain.

Bottles of 100 NDC 31722-928-01

Storage and Handling

Protect from moisture. Dispense in tight container with child-resistant closure.

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

**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 chewable tablets, 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 chewable tablets in a safe place, preferably locked, and instruct patients to not give methylphenidate hydrochloride chewable tablets 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 chewable tablets 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

Advise patients and their caregivers that methylphenidate hydrochloride chewable tablets can cause elevations of their blood pressure and pulse rate *[see Warnings and Precautions (5.3)]*.

Psychiatric Adverse Reactions

Advise patients and their caregivers that methylphenidate hydrochloride chewable tablets, 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, caregivers, and family members 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] *[see Warnings and Precautions (5.6)]*

- Instruct patients beginning treatment with methylphenidate hydrochloride chewable tablets 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 healthcare provider 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 chewable tablets.
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

Long-Term Suppression of Growth in Pediatric Patients

Advise patients, families and caregivers that methylphenidate hydrochloride chewable tablets can cause slowing of growth and weight loss *[see Warnings and Precautions (5.7)]*.

Increased Intraocular Pressure (IOP) and Glaucoma

Advise patients that IOP and glaucoma may occur during treatment with methylphenidate hydrochloride chewable tablets *[see Warnings and Precautions (5.10)]*.

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 chewable 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 (5.11)]*.

Administration Information

Advise patients to take methylphenidate hydrochloride chewable tablets with at least 8 ounces (a full glass) of water or other fluid because the tablet may swell and block the throat or esophagus which may result in choking. Advise patients to discontinue methylphenidate hydrochloride chewable tablets and seek immediate medical attention if they experience chest pain, vomiting, difficulty in swallowing, or difficulty in *breathing [see Dosage and Administration (2.2) and Warnings and Precautions (5.11)]*.

Pregnancy Registry

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

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

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

Revised: 09/2026

**MEDICATION GUIDE**
**Methylphenidate Hydrochloride**
***(meth" il fen' i date hye" droe klor' ide)***
**Chewable Tablets, CII**

**What is the most important information I should know about methylphenidate hydrochloride chewable tablets?**

**Methylphenidate hydrochloride chewable tablets may cause serious side effects, including:**

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

**Call your healthcare provider right away 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 chewable 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 chewable tablets.

- **Mental (psychiatric) problems, including:**
  - new or worse behavior or 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 chewable tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**

**What are methylphenidate hydrochloride chewable tablets?**

Methylphenidate hydrochloride chewable tablets are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older. Methylphenidate hydrochloride chewable tablets may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- a sleep disorder called narcolepsy.

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

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

**Who should not take methylphenidate hydrochloride chewable tablets?**

**Do not take methylphenidate hydrochloride chewable tablets if you or your child:**

- are allergic to methylphenidate or any of the ingredients in methylphenidate hydrochloride chewable tablets. See the end of this Medication Guide for a complete list of ingredients in methylphenidate hydrochloride chewable tablets.
- are taking or have stopped taking within the past 14 days, a medicine called a monoamine oxidase inhibitor (MAOI).
- have a condition called pheochromocytoma (a rare tumor that usually grows in the adrenal glands which are above your kidneys).

**Before taking methylphenidate hydrochloride chewable tablets tell your healthcare provider about all of your or your child's 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 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
- have trouble swallowing
- have phenylketonuria (PKU). The artificial sweetener aspartame in methylphenidate hydrochloride chewable tablets contains phenylalanine, which can be harmful to people with PKU.
- are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride chewable tablets will harm your unborn baby.
  - There is a pregnancy registry for women who are exposed to methylphenidate hydrochloride chewable tablets during pregnancy. The purpose of the registry is to collect information about the health of women exposed to methylphenidate hydrochloride chewable tablets and their baby. If you or your child becomes pregnant during treatment with methylphenidate hydrochloride chewable tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visit online at www.womensmentalhealth.org/research/pregnancyregistry/adhd-medications/.
- are breastfeeding or plan to breastfeed. Methylphenidate hydrochloride passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with methylphenidate hydrochloride chewable tablets.

**Tell your healthcare provider about all of the medicines that you or your child take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

**Especially tell your healthcare provider if you or your child take an monoamine oxidase inhibitor (MAOI).**

Know the medicines that you or your child take. Keep a list of your or your child's medicines with you to show your or your child's healthcare provider and pharmacist when you or your child get a new medicine. **Do not start any new medicine during treatment with methylphenidate hydrochloride chewable tablets without talking to your or your child's healthcare provider first.**

**How should I take methylphenidate hydrochloride chewable tablets?**

- **Take methylphenidate hydrochloride chewable tablets exactly as prescribed by your healthcare provider.** Your healthcare provider may change the dose if needed.
- **For children 6 years of age and older:**
  - Take methylphenidate hydrochloride chewable tablets 2 times a day, 30 to 45 minutes before breakfast and lunch.
- **For adults:**
  - Take methylphenidate hydrochloride chewable tablets 2 or 3 times a day, 30 to 45 minutes before a meal.
  - If you have trouble sleeping when methylphenidate hydrochloride chewable tablets is taken late in the day, take your last dose before 6 p.m.
- Chew methylphenidate hydrochloride chewable tablets well and swallow with at least 8 ounces (a full glass) of water or other liquid.
  - Do not swallow methylphenidate hydrochloride chewable tablets whole.
  - If you do not take enough liquid with methylphenidate hydrochloride chewable tablets, this can cause you to choke. Stop taking methylphenidate hydrochloride chewable tablets and get medical help right away if you or your child have chest pain, vomiting, trouble swallowing, or trouble breathing after taking methylphenidate hydrochloride chewable tablets.
- If you or your child takes too much methylphenidate hydrochloride chewable 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 chewable tablets?**

**Methylphenidate hydrochloride chewable tablets may cause serious side effects, including:**

- See **"What is the most important information I should know about methylphenidate hydrochloride chewable tablets?"**
- **Painful and prolonged erections (priapism).** Priapism that may require surgery has happened in males who take products that contain methylphenidate. **If you or your child develops 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, or 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 chewable tablets.

- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with methylphenidate hydrochloride chewable tablets. Your healthcare provider may stop your child's treatment with methylphenidate hydrochloride chewable tablets if your child is not growing or gaining weight as expected.
- **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 chewable tablets.

**The most common side effects of methylphenidate hydrochloride chewable tablets include:**

- increased heart rate
- irregular heartbeat (palpitations)
- headache
- trouble sleeping
- anxiety
- nervousness
- sweating
- weight loss
- decreased appetite
- dry mouth
- nausea
- stomach (abdominal) pain

These are not all possible side effects of methylphenidate hydrochloride chewable tablets.

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 chewable tablets?**

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

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

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

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

For more information, please contact Camber Pharmaceuticals, Inc. at 1-866-495-8330.

**What are the ingredients in methylphenidate hydrochloride chewable tablets?**

**Active ingredient:** methylphenidate hydrochloride, USP

**Inactive ingredients:** The inactive ingredients are aspartame, lactose anhydrous, microcrystalline cellulose, guar gum, grape flavor, pregelatinized starch, and stearic acid.

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

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

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 09/2026