HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use METHYLIN® Chewable Tablets safely and effectively. See full prescribing information for METHYLIN® Chewable Tablets.

METHYLIN® Chewable Tablets (methylphenidate hydrochloride), for oral use, CII
Initial U.S. Approval: 1955

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

Methylin 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 Methylin, can result in overdose and death (5.1, 9.2, 10):
- **Before prescribing Methylin, 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----------
Methylin 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----------
- Known hypersensitivity to methylphenidate or other components of Methylin (4)
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days (4)

----------WARNINGS AND PRECAUTIONS----------
- Risks to Patients with Serious Cardiac Disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac disease. (5.2)
- Increased Blood Pressure and Heart Rate: Monitor blood pressure and pulse. (5.3)
- Psychiatric Adverse Reactions: Prior to initiating Methylin, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing Methylin. (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 Methylin 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: Methylin-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 Methylin 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 Methylin, 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 Methylin 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: Methylin 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 Mallinckrodt at 1-800-778-7898 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: 1/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

Methylin 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 Methylin, 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 Methylin, 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 Methylin 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

Methylin Chewable Tablets is 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 Methylin 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 Methylin 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 Methylin 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 Methylin Chewable Tablets. If improvement is not observed after appropriate dosage adjustment over a one-month period, discontinue Methylin Chewable Tablets.

3 DOSAGE FORMS AND STRENGTHS

Chewable tablets:

- 2.5 mg of methylphenidate hydrochloride, white to cream colored, grape flavored, rounded square tablet with a convex surface, debossed with a “2.5” and “CHEW” below it on one side, and a debossed 人 on the other side
- 5 mg of methylphenidate hydrochloride, a white to cream colored, grape flavored, rounded square tablet with a convex surface, debossed with a “5” and “CHEW” below it on one side, and a debossed 人 on the other side
- 10 mg of methylphenidate hydrochloride, white to cream colored, grape flavored, scored rounded square tablet with a convex surface, debossed with a “10” and “CHEW” below it on one side, and a debossed 人 on the other side

4 CONTRAINDICATIONS

Methylin Chewable Tablets is contraindicated in patients:

- with a known hypersensitivity to methylphenidate or other components of Methylin 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)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Methylin has a high potential for abuse and misuse. The use of Methylin exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Methylin 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 Methylin, 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 Methylin, 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 Methylin in a safe place, preferably locked, and instruct patients to not give Methylin to anyone else. Throughout Methylin 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 Methylin 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 Methylin-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 Methylin 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 Methylin.

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).

Methylin-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 Methylin, 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 Methylin treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for Methylin-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 Methylin-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, Methylin-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 Methylin to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor Methylin-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 Methylin, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor Methylin-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.

5.11 Risk of Choking

Methylin Chewable Tablets may swell and block the throat or esophagus which can cause the patient to choke. Avoid use of Methylin Chewable Tablets in patients who have difficulty swallowing. Administer with at least 8 ounces of fluid *[see Dosage and Administration (2.2)]*. Discontinue Methylin 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). Methylin Chewable Tablets contain phenylalanine, a component of aspartame. Each 2.5 mg Methylin Chewable Tablet contains 0.42 mg of phenylalanine; each 5.0 mg Methylin Chewable Tablet contains 0.84 mg of phenylalanine and each 10.0 mg Methylin Chewable Tablet contains 1.68 mg of phenylalanine. Before prescribing Methylin Chewable Tablets to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including Methylin 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 Methylin *[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 Methylin.

Table 1: Drugs Having Clinically Important Interactions with Methylin

Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact:	Concomitant use of MAOIs and CNS stimulants, including Methylin, 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 Methylin with monoamine oxidase inhibitors (MAOIs) or within 14 days after discontinuing MAOI treatment is contraindicated.
Antihypertensive Drugs	
Clinical Impact:	Methylin 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 Methylin may increase the risk of sudden blood pressure and heart rate increase during surgery.
Intervention:	Avoid use of Methylin 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 Methylin, 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 Methylin, 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 Methylin

and any potential adverse effects on the breastfed infant from Methylin 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 Methylin for the treatment of ADHD have been established in pediatric patients six years of age and older. The safety and effectiveness of Methylin 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 Methylin. 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

Methylin has not been studied in the geriatric population.

8.6 Renal Impairment

Methylin has not been studied in patients with renal impairment.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Methylin Chewable Tablets contains methylphenidate, a Schedule II controlled substance.

9.2 Abuse

Methylin 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)]*. Methylin 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 Methylin, 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

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

Tolerance

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

10 OVERDOSAGE

Clinical Effects of Overdose

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

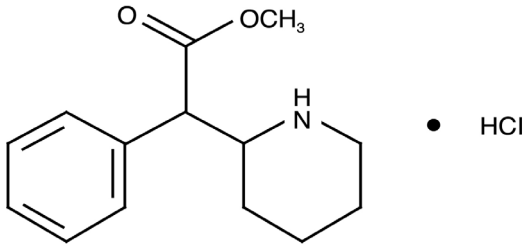
- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin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

Overdose Management

Consider the possibility of multiple drug ingestion. Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful. Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

11 DESCRIPTION

Methylin® 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.

Methylin 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).

Methylin Chewable Tablets contain the following inactive ingredients: aspartame, maltose, 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 Methylin.

The effect of dexmethylphenidate, the pharmacologically active d-enantiomer of Methylin, 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 Methylin 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 methlyphenidate pharmacokinetics was observed between Methylin 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 Methylin 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 Methylin 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 Methylin 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 Methylin Chewable Tablets have been studied in healthy adult volunteers. The mean terminal half-life ($t_{½}$) of methylphenidate following administration of 20 mg Methylin 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 Methylin administration have not been studied.

Patients with Renal Impairment
There is no experience with the use of Methylin 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 Methylin Chewable Tablets.

Patients with Hepatic Impairment
There is no experience with the use of Methylin 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 (MRDH) 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 Methylin Chewable Tablet 2.5 mg of methylphenidate hydrochloride is available as a white to cream colored, grape flavored, rounded square tablet with a convex surface, debossed with a “2.5” and “CHEW” below it on one side, and a debossed 人 on the other side.

Bottles of 100…….NDC 59630-760-10

Each Methylin Chewable Tablet 5 mg of methylphenidate hydrochloride is available as a white to cream colored, grape flavored, rounded square tablet with a convex surface, debossed with a “5” and “CHEW” below it on one side, and a debossed 人 on the other side.

Bottles of 100…….NDC 59630-761-10

Each Methylin Chewable Tablet 10 mg of methylphenidate hydrochloride is available as a white to cream colored, grape flavored, scored rounded square tablet with a convex surface, debossed with a “10” and “CHEW” below it on one side, and a debossed 人 on the other side.

Bottles of 100…….NDC 59630-762-10

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 Methylin, 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 Methylin in a safe place, preferably locked, and instruct patients to not give Methylin 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 Methylin 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 Methylin 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 Methylin, 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 Methylin 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 Methylin.
- 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 Methylin 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 Methylin *[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 Methylin. 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 Methylin 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 Methylin 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 Methylin during pregnancy *[see Use in Specific Populations (8.1)]*.

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L20M18

MEDICATION GUIDE
METHYLIN® Chewable Tablets
(METH il in)
(methylphenidate hydrochloride), CII

What is the most important information I should know about Methylin Chewable Tablets?

Methylin Chewable Tablets may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Methylin Chewable Tablets has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of Methylin 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 Methylin 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 Methylin Chewable Tablets and will monitor you or your child during treatment.
  - Methylin Chewable Tablets may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
  - Do not give Methylin Chewable Tablets to anyone else. See **"What is Methylin Chewable Tablets?"** for more information.
  - Keep Methylin Chewable Tablets in a safe place and properly dispose of any unused medicine. See **"How should I store Methylin 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 Methylin 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 Methylin 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 Methylin 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 Methylin Chewable Tablets, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What is Methylin Chewable Tablets?

Methylin Chewable Tablets is 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. Methylin 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 Methylin Chewable Tablets is safe and effective in children under 6 years of age.

Methylin 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 Methylin Chewable Tablets in a

safe place to protect it from theft. Never give your Methylin Chewable Tablets to anyone else, because it may cause death or harm them. Selling or giving away Methylin Chewable Tablets may harm others and is against the law.

Do not take Methylin Chewable Tablets if you or your child:

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

Before taking Methylin 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 Methylin Chewable Tablets contains phenylalanine, which can be harmful to people with PKU.
- are pregnant or plan to become pregnant. It is not known if Methylin Chewable Tablets will harm your unborn baby.
    - There is a pregnancy registry for women who are exposed to Methylin Chewable Tablets during pregnancy. The purpose of the registry is to collect information about the health of women exposed to Methylin Chewable Tablets and their baby. If you or your child becomes pregnant during treatment with Methylin 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. Methylin passes into breast milk. Talk to your healthcare provider about the best way to feed the baby during treatment with Methylin 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.

Methylin 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 during treatment with Methylin Chewable Tablets. Your healthcare provider will decide whether Methylin 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 Methylin Chewable Tablets without talking to your or your child's healthcare provider first.**

How should I take Methylin Chewable Tablets?

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

Methylin Chewable Tablets may cause serious side effects, including:

- See **"What is the most important information I should know about Methylin 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 Methylin Chewable Tablets.
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with Methylin Chewable Tablets. Your healthcare provider may stop your child's treatment with Methylin 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 Methylin Chewable Tablets.

The most common side effects of Methylin Chewable Tablets include:

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

These are not all possible side effects of Methylin 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 Methylin Chewable Tablets?

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

Keep Methylin Chewable Tablets and all medicines out of the reach of children.

General information about the safe and effective use of Methylin Chewable Tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Methylin Chewable Tablets for a condition for which it was not prescribed. Do not give Methylin 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 Methylin Chewable Tablets that is written for health professionals.

What are the ingredients in Methylin Chewable Tablets?
Active Ingredient: methylphenidate hydrochloride
Inactive Ingredients: aspartame, maltose, microcrystalline cellulose, guar gum, grape flavor, pregelatinized starch, and stearic acid.

Distributed by: Shionogi Inc., Florham Park, NJ 07932
Manufactured by: SpecGx LLC, Webster Groves, MO 63119 USA

For more information, you may also contact Shionogi Inc. at 1-800-849-9707 or visit the website at www.methylinrx.com.

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