**METHYLPHENIDATE HYDROCHLORIDE**- methylphenidate hydrochloride tablet
**METHYLPHENIDATE HYDROCHLORIDE SR**- methylphenidate hydrochloride tablet, film coated, extended release
Sandoz Inc

---

**HIGHLIGHTS OF PRESCRIBING INFORMATION**
These highlights do not include all the information needed to use METHYLPHENIDATE HYDROCHLORIDE tablets CII and METHYLPHENIDATE HYDROCHLORIDE sustained-release tablets CII safely and effectively. See full prescribing information for METHYLPHENIDATE HYDROCHLORIDE tablets CII and METHYLPHENIDATE HYDROCHLORIDE sustained-release tablets CII. METHYLPHENIDATE HYDROCHLORIDE tablets, for oral use, CII
METHYLPHENIDATE HYDROCHLORIDE sustained-release tablets, for oral use, CII
Initial U.S. Approval: 1955

---

**WARNING: ABUSE AND DEPENDENCE**
See full prescribing information for complete boxed warning.

- CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, other methylphenidate containing products, and amphetamines, have a high potential for abuse and dependence (5.1, 9.2, 9.3).
- Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy (5.1, 9.2)

---

**RECENT MAJOR CHANGES**
Boxed Warning 1/2019
Contraindications (4) 1/2019
Warnings and Precautions (5) 1/2019

---

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

**DOSAGE AND ADMINISTRATION**

**Methylphenidate Hydrochloride Tablets (2.2):**

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

**Methylphenidate Hydrochloride Sustained-Release Tablets (2.2):**

- May switch to methylphenidate hydrochloride sustained-release when the 8-hour dosage of methylphenidate hydrochloride sustained-release corresponds to the titrated 8-hour dosage of methylphenidate hydrochloride
- Must be swallowed whole and never crushed or chewed

**DOSAGE FORMS AND STRENGTHS**

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

**CONTRAINDICATIONS**

- Known hypersensitivity to methylphenidate or other product components of methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release (4)
- Concurrent treatment with a monoamine oxidase inhibitor (MAOI), or use of an MAOI within the preceding 14 days (4)

**WARNINGS AND PRECAUTIONS**
• **Serious Cardiovascular Events**: Sudden death has been reported in association with CNS-stimulant treatment at usual doses in pediatric patients with structural cardiac abnormalities or other serious heart problems. In adults, sudden death, stroke, and myocardial infarction have been reported. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm arrhythmias, or coronary artery disease (5.2).

• **Blood Pressure and Heart Rate Increases**: Monitor blood pressure and pulse. Consider the benefits and risk in patients for whom an increase in blood pressure or heart rate would be problematic (5.3).

• **Psychiatric Adverse Reactions**: Use of stimulants may cause psychotic or manic symptoms in patients with no prior history or exacerbation of symptoms in patients with preexisting psychiatric illness. Evaluate for preexisting psychotic or bipolar disorder prior to methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release use (5.4).

• **Priapism**: Cases of painful and prolonged penile erections, and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed (5.5).

• **Peripheral Vasculopathy, including Raynaud’s Phenomenon**: Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Careful observation for digital changes is necessary during treatment with ADHD stimulants (5.6).

• **Long-Term Suppression of Growth**: Monitor height and weight at appropriate intervals in pediatric patients (5.7).

---

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 Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---

• Antihypertensive drugs: Monitor blood pressure. Adjust dosage of antihypertensive drug as needed (7)

• Halogenated anesthetics: Avoid use of methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release on the day of surgery if halogenated anesthetics will be used (7)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide. Revised: 5/2019

---

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: ABUSE AND DEPENDENCE

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

  2.1 Pretreatment Screening
  2.2 General Dosing Information
  2.3 Dose Reduction and Discontinuation

3 DOSAGE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

  5.1 Potential for Abuse and Dependence
  5.2 Serious Cardiovascular Reactions
  5.3 Blood Pressure and Heart Rate Increases
  5.4 Psychiatric Adverse Reactions
  5.5 Priapism
  5.6 Peripheral Vasculopathy, including Raynaud’s Phenomenon
  5.7 Long-Term Suppression of Growth

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

  7.1 Clinically Important Interactions with Methylphenidate Hydrochloride and Methylphenidate Hydrochloride Sustained-Release

8 USE IN SPECIFIC POPULATIONS
FULL PRESCRIBING INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Warning and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)].

1 INDICATIONS AND USAGE

Methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release are indicated for the treatment of:

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

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating pediatric patients and adults with central nervous system (CNS) stimulants, including methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release, assess for the presence of cardiac disease (i.e., perform a careful history including family history of sudden death or ventricular arrhythmia, and physical examination) [see Warnings and Precautions (5.2)].

Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy. Maintain careful prescription records, educate patients about abuse, monitor for signs of abuse and overdose, and periodically reevaluate the need for methylphenidate hydrochloride or
methylphenidate hydrochloride sustained-release use [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9)].

2.2 General Dosing Information

Methylphenidate Hydrochloride Tablets

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

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

Methylphenidate Hydrochloride Sustained-Release Tablets

Methylphenidate hydrochloride sustained-release tablets have a duration of action of approximately 8 hours. Therefore, methylphenidate hydrochloride sustained-release tablets may be used in place of methylphenidate hydrochloride tablets when the 8-hour dosage of methylphenidate hydrochloride sustained-release corresponds to the titrated 8-hour dosage of methylphenidate hydrochloride.

Methylphenidate hydrochloride sustained-release tablets must be swallowed whole and never crushed or chewed.

Pharmacological treatment of ADHD may be needed for extended periods. Periodically reevaluate the long-term use of methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, and adjust dosage as needed.

2.3 Dose Reduction and Discontinuation

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

3 DOSAGE FORMS AND STRENGTHS

Tablets

- 5 mg-round, yellow (SZ imprinted on one side and 783 on the other)
- 10 mg, round, pale green, scored (SZ imprinted on one side and 789 on the other)
- 20 mg, round, pale yellow, scored (SZ imprinted on one side and 790 on the other)

Sustained-Release Tablets

- 20 mg sustained-release tablets, round, white to off-white, film coated (SZ and 780 printed in black ink on one side)

4 CONTRAINDICATIONS

- Hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with methylphenidate [see Adverse Reactions (6.1)].
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following
WARNINGS AND PRECAUTIONS

5.1 Potential for Abuse and Dependence
CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence.

Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Boxed Warning, Drug Abuse and Dependence (9.2, 9.3)].

5.2 Serious Cardiovascular Reactions
Sudden death, stroke and myocardial infarction have been reported in adults with CNS stimulant treatment at recommended doses. Sudden death has been reported in pediatric patients with structural cardiac abnormalities and other serious heart problems taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, and other serious heart problems.

Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release treatment.

5.3 Blood Pressure and Heart Rate Increases
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). Individuals may have larger increases. Monitor all patients for hypertension and tachycardia.

5.4 Psychiatric Adverse Reactions
Exacerbation of Preexisting Psychosis
CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder
CNS stimulants may induce a manic or mixed mood episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms
CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release. 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 in placebo-treated patients.

5.5 Priapism
Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate products in both pediatric and adult patients. Priapism was not reported with drug initiation but developed after some time on the drug, often subsequent to an increase in dose. Priapism has also appeared during a period of drug withdrawal (drug holidays or during discontinuation). Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical discontinuation of treatment with an MAOI, because of the risk of hypertensive crises [see DrugInteractions (7.1)].
attention.

5.6 Peripheral Vasculopathy, including Raynaud’s Phenomenon

CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud’s phenomenon, were observed in postmarketing reports at different times and at therapeutic doses in all age groups throughout the course of treatment. Signs and symptoms generally improve after reduction in dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with ADHD stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

5.7 Long-Term Suppression of Growth

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 patients over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated pediatric patients (i.e., treatment for 7 days per week throughout the year) have 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 period of development.

Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

6 ADVERSE REACTIONS

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

- Abuse and Dependence [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 and methylphenidate hydrochloride sustained-release [see Contraindications (4)]
- Hypertensive crisis with Concomitant Use of Monoamine Oxidase Inhibitors [see Contraindications (4), Drug Interactions (7.1)]
- Serious Cardiovascular Reactions [see Warnings and Precautions (5.2)]
- Blood Pressure and Heart Rate Increases [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 [see Warnings and Precautions (5.7)]

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

Adverse Reactions Reported with Methylphenidate Hydrochloride and Methylphenidate Hydrochloride Sustained-Release
Infections and Infestations: nasopharyngitis

Blood and the Lymphatic System Disorders: leukopenia, thrombocytopenia, anemia

Immune System Disorders: hypersensitivity reactions, including angioedema and anaphylaxis

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

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

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

Eye Disorders: blurred vision, difficulties in visual accommodation

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

Respiratory, Thoracic and Mediastinal Disorders: cough

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

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

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

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

Investigations: weight loss (adult ADHD patients)

Additional Adverse Reactions Reported with Other Methylphenidate-Containing Products

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

Blood and Lymphatic Disorders: pancytopenia

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

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

Nervous System Disorders: migraine

Eye Disorders: diplopia, mydriasis

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

Vascular Disorders: peripheral coldness, Raynaud's phenomenon

Respiratory, Thoracic and Mediastinal Disorders: pharyngolaryngeal pain, dyspnea

Gastrointestinal Disorders: diarrhea, constipation

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

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

Renal and Urinary Disorders: hematuria

Reproductive System and Breast Disorders: gynecomastia

General Disorders: fatigue, hyperpyrexia
General Disorders: fatigue, hyperpyrexia

Urogenital Disorders: priapism

7 DRUG INTERACTIONS

7.1 Clinically Important Interactions with Methylphenidate Hydrochloride and Methylphenidate Hydrochloride Sustained-Release

Table 1 presents clinically important drug interactions with methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release.

<table>
<thead>
<tr>
<th>Monoamine Oxidase Inhibitors (MAOI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Impact</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Examples</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Antihypertensive Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Impact</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Examples</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Halogenated Anesthetics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical Impact</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Examples</strong></td>
</tr>
</tbody>
</table>

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C

In 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. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 40 times the maximum recommended human dose (MRHD) on a mg/m² basis. The no-effect level for embryo-fetal development in rabbits was 60 mg/kg/day (11 times the MRHD on a mg/m² basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (7 times the MRHD on a mg/m² basis), which was also
maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (2 times the MRHD on a mg/m² basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (4 times the MRHD on a mg/m² basis), but no other effects on postnatal development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (equal to the MRHD on a mg/m² basis).

Adequate and well-controlled studies in pregnant women have not been conducted. Methylphenidate hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers
It is not known whether methylphenidate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if methylphenidate hydrochloride is administered to a nursing woman.

8.4 Pediatric Use
The safety and effectiveness of methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release for the treatment of ADHD have been established in pediatric patients 6 to 17 years. The safety and effectiveness of methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release in pediatric patients less than 6 years have not been established.

The long-term efficacy of methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release in pediatric patients has not been established.

Long-Term Suppression of Growth
Growth should be monitored during treatment with stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release. Pediatric patients who are not growing or gaining weight as expected may need to have their treatment interrupted [see Warnings and Precautions (5.7)].

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 6 times the MRHD on a mg/m² basis) or greater, and a deficit in the acquisition of a specific learning task was seen in females exposed to the highest dose (12 times the MRHD on a mg/m² basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (half the MRHD on a mg/m² 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.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance
Methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release are Schedule II controlled substance.

9.2 Abuse
CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, have a high potential for abuse. Abuse is characterized by impaired control over drug use despite harm, and craving.

Signs and symptoms of CNS stimulant abuse include increased heart rate, respiratory rate, blood pressure, and/or 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. Abusers of CNS stimulants may chew, snort, inject, or use other unapproved routes of administration which may result in overdose and death [see Overdosage (10)].

To reduce the abuse of CNS stimulants including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants [see How Supplied/Storage and Handling (16)], monitor for signs of abuse while on therapy, and reevaluate the need for methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release use.

9.3 Dependence

Tolerance

Tolerance (a state of adaptation in which exposure to a drug results in a reduction of the drug’s desired and/or undesired effects over time) can occur during chronic therapy with CNS stimulants, including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release.

Dependence

Physical dependence (which is manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) may occur in patients treated with CNS stimulants including methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include dysphoric mood; fatigue; vivid, unpleasant dreams; insomnia or hypersonnia; increased appetite; and psychomotor retardation or agitation.

10 OVERDOSAGE

Human Experience

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hyperreflexia, muscle twitching, convulsions (which may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, hypotension, tachypnea, mydriasis, dryness of mucous membranes, and rhabdomyolysis.

Overdose Management

Consult with a Certified Poison Control Center (1-800-222-1222) for the latest recommendations.

11 DESCRIPTION

Methylphenidate hydrochloride, USP is a mild central nervous system (CNS) stimulant, available as tablets of 5, 10, and 20 mg for oral administration; methylphenidate hydrochloride, USP sustained-release is available for oral administration as 20 mg tablets. Methylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride, and its structural formula is
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. Its molecular weight is 269.77.

Inactive Ingredients. Methylphenidate hydrochloride tablets, USP: D&C Yellow No. 10 (5mg and 20mg tablets), FD&C Green No. 3 (10mg tablets), lactose, magnesium stearate, polyethylene glycol, starch (5mg and 10mg tablets), sucrose, talc, and tragacanth (20mg tablets).

Methylphenidate hydrochloride sustained-release tablets, USP: cetostearyl alcohol, lactose, magnesium stearate, mineral oil, povidone, titanium dioxide, and zein.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Methylphenidate hydrochloride is a 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 is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space.

Cardiac Electrophysiology
A formal QT study has not been conducted in patients taking methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release.

The effect of dexamethylphenidate, 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 dexamethylphenidate XR 40 mg (maximum recommended adult total daily dosage) in 75 healthy volunteers.

Electrocardiograms (ECGs) were collected up to 12 hours postdose. Frederica’s method for heart rate correction was employed to derive the corrected QT interval (QTₐₗₐₜₙ₁₉). The maximum mean prolongation of QTₐₗₐₜₙ₁₉ intervals was less than 5 ms, and the upper limit of the 90% confidence interval (CI) 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
Methylphenidate hydrochloride in the SR tablets is more slowly but as extensively absorbed as in the regular tablets. Relative bioavailability of the SR tablet compared to the methylphenidate hydrochloride tablet, measured by the urinary excretion of methylphenidate hydrochloride major metabolite (α-phenyl-2-piperidine acetic acid) was 105% (49% to 168%) in children and 101% (85% to 152%) in adults. The time to peak rate in children was 1.9 hours (0.3 to 4.4 hours) for the methylphenidate hydrochloride
tablets and 4.7 hours (1.3 to 8.2 hours) for the methylphenidate hydrochloride sustained-release tablets. An average of 67% of SR tablet dose was excreted in children as compared to 86% in adults.

**Effect of Food**

After a high-fat meal, both area under the curve (AUC) (by 25 %) and C\textsubscript{max} (by 27 %) are higher. Time to C\textsubscript{max} (T\textsubscript{max}) is faster after a high-fat meal (median T\textsubscript{max}: 2.5 hours) as compared to without food (median T\textsubscript{max}: 3 hours).

**Distribution**

Binding to plasma proteins is low (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 systemic clearance is 0.40 ± 0.12 L/h/kg for d-methylphenidate and 0.73 ± 0.28 L/h/kg for l-methylphenidate.

**Metabolism**

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

**Excretion**

After oral administration, 78% to 97% of the dose is excreted in the urine and 1% to 3% in feces in the form of metabolites within 48 to 96 hours. Most of the dose is excreted in the urine as alpha-phenyl-2-piperidine acetic acid (60% to 86%). The cumulative urinary excretion of alpha-phenyl-2-piperidine acetic acid are not significantly different for methylphenidate hydrochloride sustained-release tablets.

**Studies in Specific Populations**

**Male and Female Patients**

In a clinical study involving adult subjects who received methylphenidate hydrochloride sustained-release, plasma concentrations of methylphenidate hydrochloride’s major metabolite appeared to be greater in females than in males. No gender differences were observed for methylphenidate hydrochloride plasma concentration in the same subjects.

**Racial or Ethnic Groups**

There is insufficient experience with the use of methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release to detect ethnic variations in pharmacokinetics.

**Patients with Renal Impairment**

Methylphenidate hydrochloride has not been studied in renally-impaired patients. Renal impairment is expected to have minimal effect on the pharmacokinetics of methylphenidate since less than 1% of a radiolabeled dose is excreted in the urine as unchanged compound, and the major metabolite (ritalinic acid), has little or no pharmacologic activity.

**Patients with Hepatic Impairment**

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

**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 2 times the maximum recommended human dose (MRHD) in children on mg/m² 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 4 times the MRHD on a mg/m² 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 10-fold the maximum recommended dose in adolescents on a mg/m² basis.

**16 HOW SUPPLIED/STORAGE AND HANDLING**

Tablets 5 mg-round, yellow (SZ imprinted on one side and 783 on the other)

Bottles of 100.................................................................NDC 0781-5748-01

Tablets 10 mg-round, pale green, scored (SZ imprinted on one side and 789 on the other)

Bottles of 100.................................................................NDC 0781-5749-01

Tablets 20 mg-round, pale yellow, scored (SZ imprinted on one side and 790 on the other)

Bottles of 100.................................................................NDC 0781-5753-01

Store at 20°C to 25°C (68°F to 77°F), excursions permitted 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature]

Protect from moisture.

Dispense in tight, light-resistant container (USP).

SR Tablets 20 mg-round, white to off-white, film coated (SZ and 780 printed in black ink on one side).

Bottles of 100.................................................................NDC 0781-5754-01

Store at 20°C to 25°C (68°F to 77°F), excursions permitted 15°C to 30°C (59°F to 86°F). [See USP controlled room temperature].

Protect from moisture.
Dispense in tight, light-resistant container (USP).

Disposal
Comply with local laws and regulations on drug disposal of CNS stimulants. Dispose of remaining, unused, or expired methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release by a medicine takeback program or by an authorized collector registered with the Drug Enforcement Administration. If no take-back program or authorized collector is available, mix methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release with an undesirable, nontoxic substance to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and discard methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release in the household trash.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Controlled Substance Status/High Potential for Abuse and Dependence
Advise patients that methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release are controlled substances, and they can be abused and lead to dependence. Instruct patients that they should not give methylphenidate hydrochloride or methylphenidate hydrochloride sustained-release to anyone else. Advise patients to store methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release in a safe place, preferably locked, to prevent abuse. Advise patients to comply with laws and regulations on drug disposal. Advise patients to dispose of remaining, unused, or expired methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release by a medicine take-back program if available [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.1, 9.2, 9.3), How Supplied/Storage and Handling (16)].

Serious Cardiovascular Risks
Advise patients that there is a potential serious cardiovascular risk including sudden death, myocardial infarction, stroke, and hypertension with methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release 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)].

Blood Pressure and Heart Rate Increases
Instruct patients that methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release can cause elevations of their blood pressure and pulse rate [see Warnings and Precautions (5.3)].

Psychiatric Risks
Advise patients that methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release, at recommended doses, can cause psychotic or manic symptoms, even in patients without prior history of psychotic symptoms or mania [see Warnings and Precautions (5.4)].

Priapism
Advise patients of the possibility of painful or prolonged penile erections (priapism). Instruct them to seek immediate medical attention in the event of priapism [see Warnings and Precautions (5.5)].

Circulation Problems in Fingers and Toes [Peripheral Vasculopathy, including Raynaud’s Phenomenon]
Instruct patients about the risk of peripheral vasculopathy, including Raynaud’s Phenomenon, and associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red. Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.
Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on
fingers or toes while taking methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients [see Warnings and Precautions (5.6)].

Suppression of Growth

Advise patients that methylphenidate hydrochloride and methylphenidate hydrochloride sustained-release may cause slowing of growth and weight loss [see Warnings and Precautions (5.7)].

T2019-15B
May 2019
MF0439REV0519 US

Medication Guide

<table>
<thead>
<tr>
<th>METHYLPHENIDATE HYDROCHLORIDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>(METH-il-FEN-i-date)</td>
</tr>
<tr>
<td>tablets, USP CII</td>
</tr>
</tbody>
</table>

What is the most important information I should know about methylphenidate hydrochloride? Methylphenidate hydrochloride is a federal controlled substance (CII) because it can be abused or lead to dependence. Keep methylphenidate hydrochloride in a safe place to prevent misuse and abuse. Selling or giving away methylphenidate hydrochloride may harm others and is against the law. Tell your doctor if you or your child have abused or been dependent on alcohol, prescription medicines, or street drugs.

The following have been reported with use of methylphenidate hydrochloride and other stimulant medicines:

1. **Heart-related problems:**
   - sudden death in patients who have heart problems or heart defects
   - stroke and heart attack in adults
   - increased blood pressure and heart rate

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting methylphenidate hydrochloride.

Your doctor should check you or your child’s blood pressure and heart rate regularly during treatment with methylphenidate hydrochloride.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking methylphenidate hydrochloride.

2. **Mental (Psychiatric) problems:**

All Patients

- new or worse behavior and thought problems
- new or worse bipolar illness
- new or worse aggressive behavior or hostility
- new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

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

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

What is methylphenidate hydrochloride?

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

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

Who should not take methylphenidate hydrochloride?
Methylphenidate hydrochloride should not be taken if you or your child:

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

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

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- circulation problems in fingers or toes
- if you are pregnant or plan to become pregnant. It is not known if methylphenidate hydrochloride will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- if you are breastfeeding or plan to breastfeed. Methylphenidate hydrochloride passes into your breast milk. You and your doctor should decide if you will take methylphenidate hydrochloride or breastfeed.

Tell your doctor about all of the medicines that you or your child takes including prescription and over-the-counter medicines, vitamins, and herbal supplements. Methylphenidate hydrochloride and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking methylphenidate hydrochloride.

Your doctor will decide whether methylphenidate hydrochloride can be taken with other medicines. Especially tell your doctor if you or your child takes:

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

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.
You should not take methylphenidate hydrochloride on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

**Do not start any new medicine while taking methylphenidate hydrochloride without talking to your doctor first.**

**How should methylphenidate hydrochloride be taken?**

- Take methylphenidate hydrochloride exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride is usually taken 2 to 3 times a day.
- Take methylphenidate hydrochloride 30 to 45 minutes before a meal.
- From time to time, your doctor may stop methylphenidate hydrochloride treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking methylphenidate hydrochloride.
- Children should have their height and weight checked often while taking methylphenidate hydrochloride. Methylphenidate hydrochloride treatment may be stopped if a problem is found during these check-ups.

**In case of poisoning call your poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.**

**What are the possible side effects of methylphenidate hydrochloride?**

Methylphenidate hydrochloride may cause serious side effects, including:

- See “What is the most important information I should know about methylphenidate hydrochloride?” for information on reported heart and mental problems.
- **Painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- **Circulation problems in fingers and toes** (Peripheral vasculopathy, including Raynaud’s phenomenon):
  - fingers or toes may feel numb, cool, painful
  - fingers or toes may change color from pale, to blue, to red

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

- **Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking methylphenidate hydrochloride.**
- **Slowing of growth (height and weight) in children**

**Common side effects include:**

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

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?**

- Store methylphenidate hydrochloride in a safe place and in a tightly closed container at room
General information about the safe and effective use of methylphenidate hydrochloride.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about methylphenidate hydrochloride that is written for healthcare professionals. Do not use methylphenidate hydrochloride for a condition for which it was not prescribed. Do not give methylphenidate hydrochloride to other people, even if they have the same symptoms that you have. It may harm them and it is against the law.

What are the ingredients in methylphenidate hydrochloride tablets?

Active Ingredient: methylphenidate hydrochloride, USP

Inactive Ingredients: D&C Yellow No.10 (5-mg and 20-mg tablets), FD&C Green No.3 (10-mg tablets), lactose, magnesium stearate, polyethylene glycol, starch (5-mg and 10-mg tablets), sucrose, talc, and tragacanth (20-mg tablets).

Distributed by:
Sandoz Inc.
Princeton, NJ 08540

For Medication Guides, please visit www.us.sandoz.com or call 1-800-507-2130.

T2019-63

This Medication Guide has been approved by the U.S. Food and Drug Administration.
Revised May 2019

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

Package Label – 5 mg

Rx Only NDA 0781-5748-01

Methylphenidate HCl Tablets, USP

5 mg

100 Tablets

Dispense with Medication Guide attached or provided separately.
PRINCIPAL DISPLAY PANEL
Package Label – 10 mg

Rx Only NDA 0781-5749-01

Methylphenidate HCl Tablets, USP
10 mg
100 Tablets
Dispense with Medication Guide attached or provided separately.

PRINCIPAL DISPLAY PANEL
Package Label – 20 mg

Rx Only NDA 0781-5753-01

Methylphenidate HCl Tablets, USP
20 mg
100 Tablets
Dispense with Medication Guide attached or provided separately.
METHYLPHENIDATE HYDROCHLORIDE
methylphenidate hydrochloride tablet

<table>
<thead>
<tr>
<th>Product Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Type</strong></td>
<td>HUMAN PRESCRIPTION DRUG</td>
</tr>
<tr>
<td><strong>Route of Administration</strong></td>
<td>ORAL</td>
</tr>
<tr>
<td><strong>Item Code (Source)</strong></td>
<td>NDC:0781-5754-01</td>
</tr>
<tr>
<td><strong>DEA Schedule</strong></td>
<td>CII</td>
</tr>
</tbody>
</table>
### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI) (METHYLPHENIDATE - UNII:207ZZ9QZ49)</td>
<td>METHYLPHENIDATE HYDROCHLORIDE</td>
<td>5 mg</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
<td></td>
</tr>
<tr>
<td>SUCROSE (UNII: C151H8M554)</td>
<td></td>
</tr>
<tr>
<td>TALC (UNII: 7SEV7J4R1U)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)</td>
<td></td>
</tr>
<tr>
<td>D&amp;C YELLOW NO. 10 (UNII: 35SW5USQ3G)</td>
<td></td>
</tr>
</tbody>
</table>

### Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>Score</th>
<th>Shape</th>
<th>Size</th>
<th>Flavor</th>
<th>Imprint Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>YELLOW</td>
<td>no score</td>
<td>ROUND</td>
<td>6mm</td>
<td></td>
<td>SZ;783</td>
</tr>
</tbody>
</table>

### Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0781-5748-01</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>12/31/1955</td>
<td>05/31/2022</td>
</tr>
</tbody>
</table>

### Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA authorized generic</td>
<td>NDA010187</td>
<td>12/31/1955</td>
<td>05/31/2022</td>
</tr>
</tbody>
</table>

---

**METHYLPHENIDATE HYDROCHLORIDE**
methylphenidate hydrochloride tablet

### Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
<th>DEA Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMAN PRESCRIPTION DRUG</td>
<td>NDC:0781-5749</td>
<td>CII</td>
</tr>
<tr>
<td>ORAL</td>
<td>DEEA Schedule</td>
<td>CII</td>
</tr>
</tbody>
</table>

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI) (METHYLPHENIDATE - UNII:207ZZ9QZ49)</td>
<td>METHYLPHENIDATE HYDROCHLORIDE</td>
<td>10 mg</td>
</tr>
</tbody>
</table>
# Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>FD&amp;C GREEN NO. 3 (UNII: 3P3ONR6O15S)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)</td>
<td></td>
</tr>
<tr>
<td>SUCROSE (UNII: C151H8M554)</td>
<td></td>
</tr>
<tr>
<td>TALC (UNII: 7SEV7J4RIU)</td>
<td></td>
</tr>
</tbody>
</table>

## Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>GREEN (pale green)</th>
<th>Score</th>
<th>2 pieces</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>ROUND</td>
<td>Size</td>
<td>7mm</td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
<td>Imprint Code</td>
<td>SZ,789</td>
</tr>
<tr>
<td>Contains</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0781-5749-01</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>12/31/1955</td>
<td>05/31/2022</td>
</tr>
</tbody>
</table>

## Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA authorized generic</td>
<td>NDA010187</td>
<td>12/31/1955</td>
<td>05/31/2022</td>
</tr>
</tbody>
</table>

## METHYLPHENIDATE HYDROCHLORIDE

**methylphenidate hydrochloride tablet**

## Product Information

<table>
<thead>
<tr>
<th>Product Type</th>
<th>HUMAN PRESCRIPTION DRUG</th>
<th>Item Code (Source)</th>
<th>NDC:0781-5753</th>
</tr>
</thead>
<tbody>
<tr>
<td>Route of Administration</td>
<td>ORAL</td>
<td>DEA Schedule</td>
<td>CII</td>
</tr>
</tbody>
</table>

## Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI) (METHYLPHENIDATE - UNII:207ZZ9QZ49)</td>
<td>METHYLPHENIDATE HYDROCHLORIDE</td>
<td>20 mg</td>
</tr>
</tbody>
</table>

## Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>D&amp;C YELLOW NO. 10 (UNII: 35SW5USQ3G)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>Ingredient Name</td>
<td>Basis of Strength</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------</td>
</tr>
<tr>
<td>METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI)</td>
<td>METHYLPHENIDATE HYDROCHLORIDE</td>
</tr>
</tbody>
</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)</td>
<td></td>
</tr>
<tr>
<td>MAGNESIUM STEARATE (UNII: 70097M6I30)</td>
<td></td>
</tr>
<tr>
<td>ZEIN (UNII: 80N308T1NN)</td>
<td></td>
</tr>
<tr>
<td>METHYL ALCOHOL (UNII: Y4S76JWI5)</td>
<td></td>
</tr>
<tr>
<td>MINERAL OIL (UNII: T5L8T28FGP)</td>
<td></td>
</tr>
<tr>
<td>POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)</td>
<td></td>
</tr>
<tr>
<td>TITANIUM DIOXIDE (UNII: 15FIX9V2JP)</td>
<td></td>
</tr>
<tr>
<td>LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)</td>
<td></td>
</tr>
</tbody>
</table>
Product Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>WHITE (white to off-white)</td>
</tr>
<tr>
<td>Shape</td>
<td>ROUND</td>
</tr>
<tr>
<td>Flavor</td>
<td></td>
</tr>
<tr>
<td>Contains</td>
<td></td>
</tr>
<tr>
<td>Score</td>
<td>no score</td>
</tr>
<tr>
<td>Size</td>
<td>7mm</td>
</tr>
<tr>
<td>Imprint Code</td>
<td>SZ;780</td>
</tr>
</tbody>
</table>

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NDC:0781-5754-01</td>
<td>100 in 1 BOTTLE; Type 0: Not a Combination Product</td>
<td>03/31/1982</td>
<td>04/30/2017</td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Marketing Category</th>
<th>Application Number or Monograph Citation</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA authorized generic</td>
<td>NDA018029</td>
<td>03/31/1982</td>
<td>04/30/2017</td>
</tr>
</tbody>
</table>

Labeler - Sandoz Inc (005387188)

Registrant - Novartis Pharmaceuticals Corporation (002147023)

Revised: 5/2019