METHYLPHENIDATE HYDROCHLORIDE- methylphenidate hydrochloride tablet
Neolpharma, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use methylphenidate hydrochloride tablets safely and effectively. See full prescribing information for methylphenidate hydrochloride tablets.

Methylphenidate hydrochloride tablets, for oral use, CII
Initial U.S. Approval: 1955

WARNING: ABUSE AND DEPENDENCE

See full prescribing information for complete boxed warning.

- **CNS stimulants, including methylphenidate hydrochloride tablets, 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).**

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

- Pediatric Patients 6 Years and Older: Start with 5 mg twice daily (before breakfast and lunch), titrating the dose weekly in 5- to 10-mg increments. Dosages above 60 mg/day are not recommended (2.2).
- Adults: Average daily dosage is 20 mg to 30 mg, administered 2 or 3 times daily, preferably 30 to 45 minutes before meals. Maximum total daily dosage is 60 mg (2.2).

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

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

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 Neolpharma, Inc. at 1-844-200-4163 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.** (6)

DRUG INTERACTIONS

- Antihypertensive Drugs: Monitor blood pressure. Adjust dosage of antihypertensive drug as needed (7.1).
- Halogenated Anesthetics: Avoid use of methylphenidate hydrochloride tablets on the day of surgery if halogenated anesthetics will be used (7.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 9/2021

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FULL PRESCRIBING INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including methylphenidate hydrochloride tablets, 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 Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)]*.

1 INDICATIONS AND USAGE

Methylphenidate hydrochloride tablets are indicated for the treatment of:

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

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Screening

Prior to treating pediatric patients and adults with central nervous system (CNS) stimulants, including methylphenidate hydrochloride tablets, 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 tablets use *[see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2, 9.3)]*.

2.2 General Dosing Information

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

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

Pharmacological treatment of ADHD may be needed for extended periods. Periodically reevaluate the long-term use of methylphenidate hydrochloride tablets, 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 tablets. If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

3 DOSAGE FORMS AND STRENGTHS

- ***Tablets 5 mg-*** yellow, round, uncoated tablets debossed with a logo and identification number “NP018” on one side and “5” on the other side.
- ***Tablets 10 mg-*** white, round, uncoated, partially scored tablets debossed with a logo and identification number “NP019” on one side and “10” on the other side.
- ***Tablets 20 mg-*** light yellow, round, uncoated, partially scored tablets debossed with a logo and identification number “NP020” on one side and “20” on the other side.

4 CONTRAINDICATIONS

- Hypersensitivity to methylphenidate or other components of methylphenidate hydrochloride tablets. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported in patients treated with methylphenidate *[see Adverse Reactions (6.1)]*.
- Concomitant treatment with monoamine oxidase inhibitors (MAOIs), or within 14 days following discontinuation of treatment with an MAOI, because of the risk of hypertensive crises *[see Drug Interactions (7.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Potential for Abuse and Dependence

CNS stimulants, including methylphenidate hydrochloride tablets, 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 tablets 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 beats per minute). 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 tablets. 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 attention.

5.6 Peripheral Vasculopathy, Including Raynaud’s Phenomenon

CNS stimulants, including methylphenidate hydrochloride tablets, 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 tablets. 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 tablets *[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 tablets, and other methylphenidate products were identified in clinical trials, spontaneous reports, and literature. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

Adverse Reactions Reported With Methylphenidate Hydrochloride Tablets

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 choreoatheetoid 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 tablets 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

Urogenital Disorders: priapism

7 DRUG INTERACTIONS

7.1 Clinically Important Interactions With Methylphenidate Hydrochloride Tablets

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

Table 1: Clinically Important Drug Interactions with Methylphenidate Hydrochloride Tablets

Monoamine Oxidase Inhibitors (MAOI)	
Clinical Impact	Concomitant use of MAOIs and CNS stimulants, including methylphenidate hydrochloride tablets can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure *[see Contraindications (4)]*.
Intervention	Concomitant use of methylphenidate hydrochloride tablets with MAOIs or within 14 days after discontinuing MAOI treatment is contraindicated.
Examples	selegiline, tranylcypromine, isocarboxazid, phenelzine, linezolid, methylene blue
Antihypertensive Drugs	
Clinical Impact	Methylphenidate hydrochloride tablets may decrease the effectiveness of drugs used to treat hypertension *[see Warnings and Precautions (5.3)].*
Intervention	Monitor blood pressure and adjust the dosage of the antihypertensive drug as needed.
Examples	Potassium-sparing and thiazide diuretics, calcium channel blockers, angiotensin-converting-enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), beta blockers, centrally acting alpha-2 receptor agonists
Halogenated Anesthetics	
Clinical Impact	Concomitant use of halogenated anesthestics and methylphenidate hydrochloride tablets may increase the risk of sudden blood pressure and heart rate increase during surgery.
Intervention	Avoid use of methylphenidate hydrochloride tablets in patients being treated with anesthetics on the day of surgery.
Examples	halothane, isoflurane, enflurane, desflurane, sevoflurane
Risperidone	
	Combined use of methylphenidate with risperidone when there is a change

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

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ADHD medications, including methylphenidate hydrochloride tablets, during pregnancy. Healthcare providers are encouraged to register patients by calling the National Pregnancy Registry for ADHD Medications at 1-866-961-2388 or visit https://womensmentalhealth.org/adhd-medications/.

Risk Summary

Published studies and postmarketing reports on methylphenidate use during pregnancy have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. There may be risks to the fetus associated with the use of CNS stimulants use during pregnancy *(see Clinical Considerations)*.

No effects on morphological development were observed in embryo-fetal development studies with oral administration of methylphenidate to pregnant rats and rabbits during organogenesis at doses up to 10 and 15 times, respectively, the maximum recommended human dose (MRHD) of 60 mg/day given to adolescents on a mg/m ^{2} basis. However, spina bifida was observed in rabbits at a dose 52 times the MRHD given to adolescents. A decrease in pup body weight was observed in a pre- and post-natal development study with oral administration of methylphenidate to rats throughout pregnancy and lactation at doses 6 times the MRHD given to adolescents *(see Data)*.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

CNS stimulants, such as methylphenidate hydrochloride tablets, can cause vasoconstriction and thereby decrease placental perfusion. No fetal and/or neonatal adverse reactions have been reported with the use of therapeutic doses of methylphenidate during pregnancy; however, premature delivery and low birth weight infants have been reported in amphetamine-dependent mothers.

Data

Animal Data

In embryo-fetal development studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Malformations (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 52 times the MRHD of 60 mg/day given to adolescents on a mg/m ^{2} basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (15 times the MRHD given to adolescents on a mg/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 (10 times the MRHD of 60 mg/day given to adolescents 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 (3 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 (6 times the MRHD of 60 mg/day given to adolescents on a mg/m ^{2} basis), but no other effects on postnatal development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (~2 times the MRHD given to adolescents on a mg/m ^{2} basis).

8.2 Lactation

Risk Summary

Limited published literature, based on milk sampling from seven mothers reports that methylphenidate is present in human milk, which resulted in infant doses of 0.16% to 0.7% of the maternal weight-adjusted dosage and a milk/plasma ratio ranging between 1.1 and 2.7. There are no reports of adverse effects on the breastfed infant and no effects on milk production. Long-term neurodevelopmental effects on infants from stimulant exposure are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for methylphenidate hydrochloride tablets and any potential adverse effects on the breastfed infant from methylphenidate hydrochloride tablets or from the underlying maternal condition.

Clinical Considerations

Monitor breastfeeding infants for adverse reactions, such as agitation, insomnia, anorexia, and reduced weight gain.

8.4 Pediatric Use

The safety and effectiveness of methylphenidate hydrochloride tablets for the treatment of ADHD have been established in pediatric patients 6 to 17 years.

The safety and effectiveness of methylphenidate hydrochloride tablets in pediatric patients less than 6 years have not been established.

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

Long-Term Suppression of Growth

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

Juvenile Animal Toxicity Data

Rats treated with methylphenidate early in the postnatal period through sexual maturation demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females only. The doses at which these findings were observed are at least 4 times the MRHD of 60 mg/day given to children on a mg/m ^{2} basis.

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 was 5 mg/kg/day (approximately 0.5 times the MRHD given to children on a mg/m ^{2} basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.

8.5 Geriatric Use

Methylphenidate hydrochloride tablets have not been studied in the geriatric population.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Methylphenidate hydrochloride tablets contain methylphenidate hydrochloride, a Schedule II controlled substance.

9.2 Abuse

CNS stimulants, including methylphenidate hydrochloride tablets, 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 tablets, 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 tablets 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 tablets.

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 tablets. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include dysphoric mood; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; 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.

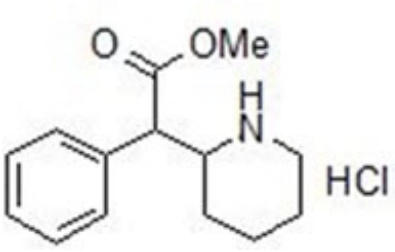
Overdose Management

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

11 DESCRIPTION

Methylphenidate hydrochloride tablets contain methylphenidate hydrochloride, a CNS stimulant. It is available as tablets of 5 mg, 10 mg, and 20 mg strength for oral administration.

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 g/mol.

Methylphenidate hydrochloride tablets contain the following inactive ingredients: lactose monohydrate, silicified microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate and D&C Yellow #10 (5 mg and 20 mg tablets).

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 blocks 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 tablets.

The effect of dexmethylphenidate, the pharmacologically active *d*-enantiomer of methylphenidate hydrochloride tablets, on the QT interval was evaluated in a double-blind, placebo- and open-label active (moxifloxacin)-controlled study following single doses of dexmethlyphenidate XR 40 mg (maximum recommended adult total daily dosage) 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

The time to peak rate in children was 1.9 hours (0.3 to 4.4 hours) for the

methylphenidate hydrochloride tablets.

Effect of Food

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

Studies in Specific Populations

Male and Female Patients

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

Racial or Ethnic Groups

There is insufficient experience with the use of methylphenidate hydrochloride tablets to detect ethnic variations in pharmacokinetics.

Patients with Renal Impairment

Methylphenidate hydrochloride tablets 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 tablets 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, and 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 MRHD of 60 mg/day given to children on 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 4 times the MRHD (children) 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 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 times the MRHD of 60 mg/day given to adolescents on a mg/m ^{2} basis.

16 HOW SUPPLIED/STORAGE AND HANDLING

Tablets 5 mg- yellow, round, uncoated tablets debossed with a logo and identification number “NP018” on one side and “5” on the other side.

Bottles of 100 .....NDC 55466-101-12

Tablets 10 mg- white, round, uncoated, partially scored tablets debossed with a logo and identification number “NP019” on one side and “10” on the other side.

Bottles of 100 .....NDC 55466-102-12

Tablets 20 mg- light yellow, round, uncoated, scored tablets debossed with a logo and identification number “NP020” on one side and “20” on the other side.

Bottles of 100 .....NDC 55466-103-12

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

Protect from light.

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 tablets 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 tablets 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 tablets 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 tablets are a controlled substances, and they can be abused and lead to dependence. Instruct patients that they should not give methylphenidate hydrochloride tablets to anyone else. Advise patients to store methylphenidate hydrochloride tablets 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 tablets 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 tablets use. Instruct patients to contact a healthcare provider immediately if they develop symptoms, such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease *[see Warnings and Precautions (5.2)]*.

Blood Pressure and Heart Rate Increases

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

Psychiatric Risks

Advise patients that methylphenidate hydrochloride tablets, at recommended doses, can

cause psychotic or manic symptoms, even in patients without prior history of psychotic symptoms or mania *[see Warnings and Precautions (5.4)].*

Priapism

Advise patients 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 tablets. 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 tablets may cause slowing of growth and weight loss *[see Warnings and Precautions (5.7)]*.

Pregnancy Registry

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

Manufactured and Distributed by:

Neolpharma, Inc.

Caguas, Puerto Rico, 00725, USA

PP10102

MEDICATION GUIDE

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

What is the most important information I should know about methylphenidate hydrochloride tablets?
Methylphenidate hydrochloride tablets are a federal controlled substance (CII) because it can be abused or lead to dependence. Keep methylphenidate hydrochloride tablets in a safe place to prevent misuse and abuse. Selling or giving away methylphenidate hydrochloride tablets 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 tablets.

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

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 tablets.

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 tablets, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What are methylphenidate hydrochloride tablets?

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

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

Who should not take methylphenidate hydrochloride tablets?

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

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

monoamine oxidase inhibitor (MAOI).

Methylphenidate hydrochloride tablets may not be right for you or your child. Before starting methylphenidate hydrochloride tablets, tell your or your child's 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 tablets will harm your unborn baby.

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

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

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 tablets and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking methylphenidate hydrochloride tablets. Your doctor will decide whether methylphenidate hydrochloride tablets 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 tablets on the day of your operation if a certain type of anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

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

How should methylphenidate hydrochloride tablets be taken?

- Take methylphenidate hydrochloride tablets exactly as prescribed. Your doctor may adjust the dose until it is right for you or your child.
- Methylphenidate hydrochloride tablets are usually taken 2 to 3 times a day.
- Take methylphenidate hydrochloride tablets 30 to 45 minutes before a meal.
- From time-to-time, your doctor may stop methylphenidate hydrochloride tablets 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 tablets.
- Children should have their height and weight checked often while taking methylphenidate hydrochloride tablets. Methylphenidate hydrochloride tablets 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 tablets?

Methylphenidate hydrochloride tablets may cause serious side effects, including:

- see **"What is the most important information I should know about methylphenidate hydrochloride tablets?"** for information on reported heart and mental problems.
- **painful and prolonged erections (priapism)** have occurred with methylphenidate. If you or your child develops priapism, seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- **circulation problems in fingers and toes** (peripheral vasculopathy, including Raynaud's phenomenon):

o fingers or toes may feel numb, cool, painful
o 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 tablets.**
- **Slowing of growth (height and weight) in children**

Common side effects include:

• fast heart beat • abnormal heartbeat • headache • trouble sleeping • nervousness (palpitations)
• 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 tablets?

- Store methylphenidate hydrochloride tablets in a safe place and in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.
- Dispose of remaining, unused, or expired methylphenidate hydrochloride tablets by a medicine take-back program at authorized collection sites, such as retail pharmacies, hospital or clinic pharmacies, and law enforcement locations. If no take-back program or authorized collector is available, mix methylphenidate hydrochloride tablets with an undesirable, nontoxic substance, such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container, such as a sealed plastic bag and throw away (discard) methylphenidate hydrochloride tablets in the household trash.
- **Keep methylphenidate hydrochloride tablets and all medicines out of the**

reach of children.

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

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

What are the ingredients in methylphenidate hydrochloride tablets?

Active ingredient: methylphenidate HCl, USP

Inactive ingredients: lactose monohydrate, silicified microcrystalline cellulose, sodium lauryl sulfate, magnesium stearate and D&C Yellow #10 (5-mg and 20-mg tablets)

Manufactured and Distributed by:
Neolpharma, Inc.
Caguas, Puerto Rico, 00725, USA

For more information and request for additional copies of the Medication Guide, call 1-844-200-4163.

MG10102

This Medication Guide has been approved by the U.S. Food and Drug Administration
Revised: 09/2021



METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55466-101
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI)	METHYLPHENIDATE	5 mg

(METHYLPHENIDATE - UNII:207ZZ9QZ49)	HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	yellow	**Score**	no score
Shape	ROUND	**Size**	59mm
Flavor		**Imprint Code**	NP018;5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55466-101-12	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208737	12/29/2023	

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55466-102
Route of Administration	ORAL	**DEA Schedule**	CII

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

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	2 pieces
Shape	ROUND	**Size**	69mm
Flavor		**Imprint Code**	NP019;10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55466-102-12	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208737	12/29/2023	

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55466-103
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPHENIDATE HYDROCHLORIDE (UNII: 4B3SC438HI) (METHYLPHENIDATE - UNII:207ZZ9QZ49)	METHYLPHENIDATE HYDROCHLORIDE	20 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	yellow (Light)	**Score**	2 pieces
Shape	ROUND	**Size**	79mm
Flavor		**Imprint Code**	NP020;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55466-103-12	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208737	12/29/2023	

Labeler - Neolpharma, Inc. (078709787)

Registrant - Neolpharma, Inc. (078709787)

Establishment

Name	Address	ID/FEI	Business Operations
Neolpharma, Inc.		078709787	manufacture(55466-101, 55466-102, 55466-103) , analysis(55466-101, 55466-102, 55466-103) , pack(55466-101, 55466-102, 55466-103) , label(55466-101, 55466-102, 55466-103)

Revised: 12/2022 Neolpharma, Inc.