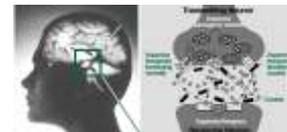
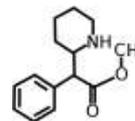


Rx METHYLPHENIDATE

(Methylphenidate is used to treat attention disorders (attention deficit hyperactivity disorder, or ADHD))



USES

Methylphenidate is used to treat attention disorders (attention deficit hyperactivity disorder, or ADHD) as part of a total treatment plan including psychological, educational and social measures. This medication is also used to treat patients with narcolepsy (a disorder of sleep regulation). When this medication is used to treat ADHD, patients may find they have increased attention, decreased impulsiveness, and decreased hyperactivity (see also Notes section). This medication is a mild stimulant that works by affecting the levels of chemicals (neurotransmitters) in the nervous system. This medication should not be used to treat simple fatigue symptoms. OTHER This section contains uses of this drug that are not listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional. This medication may also be used for treating depression in certain cases.

HOW TO USE

Read the Medication Guide provided by your pharmacist before you start using methylphenidate and each time you get a refill. If you have any questions, consult your doctor or pharmacist. This medication is best taken 30 to 45 minutes before a meal or as directed by your doctor. If loss of appetite occurs or if you experience stomach upset, it may be taken with or after meals or snacks. Use this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day. It may take up to two weeks to notice an improvement while on this drug. Use this medication exactly as prescribed. Dosage is based on your medical condition and response to therapy. Your doctor may instruct you to gradually increase or decrease your dose. Do not increase your dose, use it more frequently or use it for a longer period of time than prescribed because this drug can be habit-forming. Also, if used for a long period of time, do not suddenly stop using this without first consulting your doctor. This medication may cause withdrawal reactions, especially if it has been used regularly for a long time or in high doses. In such cases, withdrawal symptoms (such as severe depression and chronic overactivity) may occur if you suddenly stop using this medication. To prevent withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately. Though it is very unlikely to occur, this medication can also result in abnormal drug-seeking behavior (addiction/habit-forming). Do not increase your dose, take it more frequently or use it for a longer period of time than prescribed. Properly stop the medication when so directed. This will lessen the chances of becoming addicted. When used for an extended period, this medication may not work as well and may require different dosing. Talk with your doctor if this medication stops working well. Inform your doctor if your condition persists or worsens.

SIDE EFFECTS

Headache, stomach pain, loss of appetite, trouble sleeping, dizziness, nausea, vomiting, lightheadedness, irritability, nervousness, blurred vision, dry mouth, constipation or (rarely) drowsiness may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: uncontrolled movements (motor tics or tremor), verbal tics (e.g., Tourette's syndrome), weight loss, fast/pounding/irregular heartbeat, mental/mood/behavior changes (e.g., agitation, aggression, mood swings, depression, abnormal thoughts), difficulty urinating. Tell your doctor immediately if any of these rare but very serious side effects occur: signs of infection (e.g., fever, persistent sore throat), easy bruising/bleeding. Seek immediate medical attention if any of these rare but very serious side effects occur: shortness of breath, chest pain, jaw/left arm pain, fainting, seizures, sudden vision changes, weakness on one side of the body, slurred speech, confusion. A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking methylphenidate, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This medication should not be

used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: severe anxiety/tension, certain mental/mood conditions (e.g., agitation, psychosis), heart/blood vessel disease (e.g., irregular heartbeat/rhythm, coronary artery disease, angina, heart failure, cardiomyopathy), problems with heart structure (e.g., valve problems), history of heart attack or stroke, glaucoma, motor tics. Before using this medication, tell your doctor or pharmacist your medical history, especially of: high blood pressure (hypertension), family history of sudden death/irregular heartbeat/rhythm, family/personal history of mental/mood disorders (e.g., bipolar disorder, depression, psychotic disorder, suicidal thoughts), overactive thyroid (hyperthyroidism), seizures, verbal tics (diagnosis or family history of Tourette's syndrome). This drug may make you dizzy, lightheaded, (rarely) drowsy, or cause blurred vision. Do not drive, use machinery, or do any activity that requires alertness or clear vision until you are sure you can perform such activities safely. Limit alcoholic beverages. Though uncommon, depression itself can lead to thoughts or attempts of suicide. If you are being treated for depression, tell your doctor immediately if you have any suicidal thoughts, or other mental/mood changes. Keep all medical appointments so your doctor can monitor your progress closely. Children younger than 6 years may be at greater risk for the side effects of this medication. This drug may affect your child's growth rate, weight, and final adult height, especially in children younger than 6 years. To reduce the risk, the doctor may recommend temporarily stopping the medication from time to time. Check your child's weight and height, and consult your doctor or pharmacist for more details. Methylphenidate should be used during pregnancy only when clearly needed. Discuss the risks and benefits with your doctor. It is not known if methylphenidate passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS

Your healthcare professionals (e.g., doctor or pharmacist) may already be aware of any possible drug interactions and may be monitoring you for it. Do not start, stop or change the dosage of any medicine before checking with them first. Avoid taking MAO inhibitors (e.g., furazolidone, isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) within 2 weeks before or after treatment with this medication. In some cases, a serious, possibly fatal, drug interaction may occur. If you are currently using any of these medications, tell your doctor or pharmacist before starting this medication. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription/herbal products you may use, especially of: "blood thinners" (e.g., warfarin), guanethidine, phenylbutazone, drugs that can increase blood pressure (e.g., phenylephrine), anti-seizure drugs (e.g., phenobarbital, phenytoin, primidone), tricyclic antidepressants (e.g., imipramine, desipramine), SSRI antidepressants (e.g., fluoxetine, sertraline). Also report the use of drugs which might increase seizure risk when combined with this medication such as isoniazid (INH), phenothiazines (e.g., thioridazine), theophylline, or tricyclic antidepressants (e.g., amitriptyline), among others. Consult your doctor or pharmacist for details. Check the labels on all your medicines/herbal products (e.g., cough-and-cold products, diet aids) because they may contain ingredients that could increase your heart rate or blood pressure (e.g., pseudoephedrine, phenylephrine, ephedra/ma huang). Ask your pharmacist about the safe use of these products. This document does not contain all possible interactions. Therefore, before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include: confusion, agitation, sweating, flushing, wide pupils, persistent tremor, muscle twitching, hallucinations, severe headache, severe vomiting, seizures, loss of consciousness.

MISSED DOSE

If you miss a dose, take it as soon as you remember and take any remaining doses at evenly spaced times. If it is near bedtime or near time for the next dose, skip that dose and resume your regular dosing schedule. Do not double the dose to catch up.

STORAGE

Store the US product at room temperature between 59-86 degrees F (15-30 degrees C). Store the Canadian product between 36-86 degrees F (2-30 degrees C). Store the medication away from heat, moisture, and sunlight. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about

how to safely discard your product.

WARNING: Misuse or abuse of methylphenidate may result in serious (possibly fatal) heart and blood pressure problems.

Methylphenidate should be given cautiously to emotionally unstable patients, especially if there is a history of alcohol or drug abuse. These patients may be more likely to unnecessarily increase their doses or take this medication too often. Long-term overuse of this medication may lead to reduced drug effect, drug dependence, and abnormal behavior.

Take this medication only by mouth. Serious mental/mood changes (e.g., psychosis) may occur, especially if this drug is abused.

If methylphenidate must be stopped, it should be stopped gradually over time. Follow your doctor's instructions on how to gradually lower the dose. In some patients, long-term monitoring may be required after the medication is stopped.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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