

INFORMATION FOR THE PATIENT

APO-METHYLPHENIDATE (Methylphenidate Hydrochloride Tablets USP)

APO-METHYLPHENIDATE SR (Methylphenidate Hydrochloride Extended Release Tablets USP)

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

ATTENTION- DEFICIT HYPERACTIVITY DISORDER (ADHD)

This leaflet is part III of a three-part "Product Monograph" published when APO-METHYLPHENIDATE / APO-METHYLPHENIDATE SR was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about APO-METHYLPHENIDATE / APO-METHYLPHENIDATE SR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

APO-METHYLPHENIDATE is used in two different medical conditions: 1) Attention-Deficit Hyperactivity Disorder (ADHD) and 2) Narcolepsy. Information on the use of APO-METHYLPHENIDATE in each of these conditions is given in two separate leaflets. Please refer to the appropriate one for information suited to your needs.

This leaflet is specifically for information on the use of APO-METHYLPHENIDATE in Attention-Deficit Hyperactivity Disorder (ADHD)

What the medication is used for:

The doctor has prescribed APO-METHYLPHENIDATE for your child's/ your behavioural condition known as Attention-Deficit Hyperactivity Disorder (ADHD).

ADHD is a behavioural disorder in children and adolescents. It has been called by many other names including: Attention Deficit Disorder, Hyperkinetic Disorder, Minimal Brain Dysfunction, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction and Psycho-organic Syndrome of Children.

Children who suffer from ADHD show behavioural problems such as difficulty concentrating, impulsiveness and restlessness. They may fail at school although they may have adequate intelligence. Such children may be unpopular among children of the same age because of their clumsiness, intrusive behaviour and failure to follow the rules of games. Many prefer to be friends with younger children. Parents often feel that these children need more coaching and supervising than their brothers and sisters in most daily activities.

Discipline usually cannot change such children's behaviour. Teachers complain about their disruptiveness and constant need for attention. Most children with ADHD do not complain of any problems; therefore, these children may not receive medical help unless the teacher(s) or parent(s) are aware of the nature of the problem. Medical exams, psychological and educational tests are all necessary in diagnosing ADHD.

What it does:

APO-METHYLPHENIDATE belongs to a group of medicines called central nervous system stimulants. When used in ADHD, APO-METHYLPHENIDATE improves behaviour by reducing restlessness and increasing attention.

APO-METHYLPHENIDATE, however, will not cure ADHD. Treatment with APO-METHYLPHENIDATE or other stimulants should always be combined with other treatment measures, such as psychological counselling and educational tutoring by skilled and experienced therapists.

When it should not be used:

You/ your child should not take APO-METHYLPHENIDATE if you/they have the following conditions such as

- a previous allergy to a medicinal ingredient, methylphenidate, or any of the non-medicinal ingredients
- heart disorders
- thyroid disorders
- glaucoma (increased eye pressure)
- agitation
- tension
- anxiety
- motor tics or family history or diagnosis of Tourette's syndrome

And/or

- are taking a monoamine oxidase inhibitor (MAO) or have discontinued an MAO in the last 14 days.

What the medicinal ingredient is:

Methylphenidate hydrochloride

What the important nonmedicinal ingredients are:

APO-METHYLPHENIDATE 5 mg Tablets: Anhydrous lactose, magnesium stearate and sunset yellow aluminum lake 40%.

APO-METHYLPHENIDATE 10 mg Tablets: Anhydrous lactose, D&C yellow #10, FD&C blue #1 and magnesium stearate.

APO-METHYLPHENIDATE 20 mg Tablets: Anhydrous lactose, D&C yellow #10 and magnesium stearate.

APO-METHYLPHENIDATE SR 20 mg Tablets: Colloidal silicon dioxide, hydroxypropyl methylcellulose and magnesium stearate.

What dosage forms it comes in:

APO-METHYLPHENIDATE tablets are available in 5 mg, 10 mg and 20 mg strengths. APO-METHYLPHENIDATE SR tablets are available in 20 mg strength.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Drug Abuse and Dependence

Abuse of APO-METHYLPHENIDATE (SR) can lead to dependence. Tell your doctor if you have ever abused or been dependent on alcohol or drugs, or if you are now abusing or dependent on alcohol or drugs.

Sudden death has been reported in association with stimulant drugs for ADHD treatment in children with structural heart abnormalities. APO-METHYLPHENIDATE or APO-METHYLPHENIDATE SR generally should not be used in patients with known structural heart abnormalities.

APO-METHYLPHENIDATE should not be used in children under 6 years of age.

APO-METHYLPHENIDATE should not be used during pregnancy. Mothers taking APO-METHYLPHENIDATE should not breast-feed their babies.

Before you/your child uses APO-METHYLPHENIDATE talk to your doctor or pharmacist if you /your child suffer from:

- Depression, or a history of severe depression, psychosis, drug or alcohol abuse.
- Normal tiredness.
- Seizures.
- High blood pressure.
- Other medical problems.

And /or

- Have Structural heart abnormalities.
- Have a family history of sudden death or death related to heart problems..
- Do strenuous exercise.
- Take other stimulant drugs.
- Have motions tics, verbal tics or someone in your family has motion tics, verbal tics or Tourette's syndrome.
- Have abnormal thoughts or visions, hear abnormal sounds.

APO-METHYLPHENIDATE may increase seizures in some patients with history of seizures.

It is not to be used to relieve normal tiredness.

APO-METHYLPHENIDATE may affect your ability to drive or operate machinery.

Central nervous stimulants, including APO-METHYLPHENIDATE should only be given under close medical supervision to patients whose condition has been properly diagnosed.

INTERACTIONS WITH THIS MEDICATION

Alcohol should be avoided. APO-METHYLPHENIDATE may increase seizures in some patients with a history of seizures.

It is important to tell your doctor and pharmacist if you take other medications besides APO-

INFORMATION FOR THE PATIENT

APO-METHYLPHENIDATE (Methylphenidate Hydrochloride Tablets USP)

APO-METHYLPHENIDATE SR (Methylphenidate Hydrochloride Extended Release Tablets USP)

METHYLPHENIDATE since combining drugs can sometimes result in changing the expected drug effects or cause harmful effects; including guanethidine, phenylbutazone, clonidine, antidepressants, medicines to prevent blood clots (i.e. coumarin), medicines to prevent seizures.

PROPER USE OF THIS MEDICATION

Usual dose:

APO-METHYLPHENIDATE comes in tablets to be taken by mouth. The doctor determines how much and how often your child should take APO-METHYLPHENIDATE according to their individual needs. In order for your child to receive the most benefits from APO-METHYLPHENIDATE, it is important that APO-METHYLPHENIDATE be taken only as directed by the doctor.

Take only the amount of medication at the time intervals and for the time period that the doctor has prescribed. Your child should not take more than 60 mg of APO-METHYLPHENIDATE per day. If APO-METHYLPHENIDATE SR (extended-release) tablets have been prescribed for your child, these tablets must be swallowed whole and never be crushed or chewed.

This medicine should be used only as directed by your doctor. Do not give your child more of it, do not give it more often, and do not give it for a longer time than your doctor ordered.

Missed Dose:

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

Overdose:

Get medical help immediately in cases of overdose. Go to the emergency room of the nearest hospital.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The common side effects seen with this medication are dizziness, drowsiness, difficulty in sleeping, nervousness, headache.

You/your child may experience stomach discomfort, nausea and/or loss of appetite with APO-METHYLPHENIDATE. These problems may go away with time.

Taking APO-METHYLPHENIDATE with food may reduce stomach discomfort.

APO-METHYLPHENIDATE may reduce weight gain or growth in children. To help restrict this problem to a minimum, the doctor may want to withhold APO-METHYLPHENIDATE over weekends and during vacations. APO-METHYLPHENIDATE may cause sleeplessness if taken too close to bedtime.

Other side effects not listed above may occur in some patients. If you notice any other effects, tell your doctor immediately.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Sudden high fever		√	
	Palpitations (fast or pounding heartbeat)		√	
	Vomiting	√		
	Bruising		√	
	Sore throat and fever		√	

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Breathing difficulties		√	
	Chest pain		√	
	Muscle twitching or tics		√	
	Confusion		√	
	Hallucinations		√	
	Convulsions		√	
	Increase in seizure frequency			√

HOW TO STORE IT

Protect APO-METHYLPHENIDATE from moisture and heat. Store between 15 and 30°C.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

toll-free telephone: 866-234-2345

toll-free fax 866-678-6789

By email: cadrpm@hc-sc.gc.ca

By regular mail:
Canadian Adverse Drug Reaction Monitoring Program
(CADRMP)
Health Canada
Address Locator: 0201C2
Ottawa, ON K1A 1B9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional. This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service, at 1-800-667-4708. This leaflet can also be found at <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

Date of Revision: March 27, 2006