

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Ritalin® 10 mg Tablets

Each tablet contains:

Methylphenidate Hydrochloride 10 mg

Inactive ingredients: See section 'Important information regarding some of the ingredients of the medicine' and section 6 'Further Information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) and for treatment of narcolepsy.

Therapeutic group: Central nervous system stimulant.

Ritalin tablets contain the active ingredient methylphenidate hydrochloride. Methylphenidate hydrochloride is a central nervous system stimulant.

Attention Deficit Hyperactivity Disorder (ADHD or hyperkinetic disorder) is a behavioral disorder in children, adolescents and adults. About 3% of children suffer from this disorder, which makes them unable to sit still or concentrate on tasks for any length of time. Children with this disorder may have difficulty in learning and doing homework. It may frequently be difficult to manage them both in school and at home. Adults with ADHD often find it hard to concentrate. They often feel restless, impatient, inattentive and they become bored easily. They may experience difficulty organizing their private life and work.

Ritalin is assumed to work by regulating specific chemicals in the brain that affect behavior. It helps to focus attention, shut out distraction and allows impulsive people to think before they act. If treatment is successful, it improves the natural ability of the person to be attentive.

This medicine is part of a treatment program which usually also includes psychological, educational and social therapy.

Narcolepsy is a sleep-attack disorder. It is not a normal state of fatigue. Patients with narcolepsy experience recurring attacks of irresistible day-time sleep, despite adequate night-time sleep. Narcolepsy must be diagnosed by a doctor by recording wake-sleep patterns.

Ritalin relieves excessive day-time sleepiness in patients suffering from narcolepsy.

Do not use this medicine to prevent or treat normal fatigue.

If you have any question about how Ritalin works or why this medicine has been prescribed for you or your child, refer to your doctor.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- if you are allergic (hypersensitive) to the active ingredient methylphenidate, or to any of the other ingredients the medicine contains listed in section 6 'Further Information'. Some of the symptoms of allergic reaction may include shortness of breath, wheezing or breathing difficulties; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Ritalin if you are suffering from the following medical conditions:

- periods of anxiety, tension or agitation
- Tourette's syndrome (a condition of uncontrolled body movements and speech or tics) or if you have a family history of this disorder
- increased pressure in the eye (glaucoma)
- an overactive thyroid or other thyroid problems
- heart problems such as heart attack, irregular heartbeat, chest pain (angina), heart failure, heart disease or a congenital heart problem
- very high blood pressure (hypertension) or narrowing of the arterial blood vessels (arterial occlusive disease, that can cause pain in the arms and legs)
- a rare tumor of the adrenal gland, known as pheochromocytoma

If you are unsure if you are suffering from any of the medical conditions listed above, ask the doctor.

Do not take Ritalin if you are taking a medicine from the monoamine oxidase (MAO) inhibitors group or if you took MAO inhibitors within the 14 days before starting Ritalin treatment. Taking Ritalin together with medicines from the MAO inhibitors group may cause a severe reaction, which includes a sudden rise in body temperature, extremely high blood pressure and severe convulsions.

If you are not sure if you took any of these medicines, ask the doctor.

Special warnings regarding use of the medicine:

Tell the doctor if you are allergic to any other medicine, food, dyes or preservatives.

The doctor will want to know if you are prone to allergies. Tell the doctor if you have an intolerance to lactose or gluten (also see section: 'Important information regarding some of the ingredients of the medicine').

Before treatment with Ritalin, tell the doctor if you are suffering from any of the listed medical conditions or behaviors:

- heart defects (e.g., structural cardiac abnormality)
- a family history of sudden death or irregular heartbeat
- hardening of the arteries
- any other current or previous heart problem
- abnormality of blood vessels in the brain e.g., weakening of the blood vessels (aneurysm), stroke or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illnesses
- epilepsy (seizures, convulsions or fits)
- high blood pressure
- history of addiction to alcohol, drugs or drug dependence
- tics (muscle twitching, usually in the face or shoulders) or if your brothers or sisters have tics
- acute mental disorders that cause abnormal thinking and perception (psychosis) or an unusual feeling of excitement,

hyperactivity and disinhibition (acute mania) - the doctor will tell you if you have these conditions

- psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- aggressive behavior
- suicidal thoughts or behavior

If you have any of the conditions listed above, the doctor may want to take special precautionary measures.

Additional warnings

- Ritalin may give a false-positive result when testing for drug use. This includes testing used in sports
- Some children receiving Ritalin for a long time may have a slow-down in growth, however, they will usually catch up once the treatment is stopped (also see sections: 'Duration of treatment' and 'Tests and follow-up')
- In some patients, Ritalin may cause upset stomach, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the Ritalin dose or by changing the dosing times of the tablets
- If you experience abnormally sustained or frequent and painful erections of the penis on Ritalin treatment or after treatment discontinuation, you may need urgent medical treatment. This can occur in any age group. **If this occurs, refer to a doctor immediately**
- If you are taking Ritalin with medicines that raise the serotonin level in the body (serotonergic medicines, e.g., sertraline and venlafaxine, used to treat depression), and you experience a combination of the following symptoms: restlessness, tremors, sudden muscle contractions, abnormally high fever, nausea and vomiting, stop treatment with Ritalin and these medicines and refer to your doctor immediately
- If you are about to undergo an operation, inform the doctor that you are taking Ritalin. Do not take Ritalin on the day of the operation if a certain type of anesthetic is used, since there is a chance of a sudden rise in blood pressure during the operation

Children and adolescents

The medicine is not intended for children under the age of 6.

Tests and follow-up

Be sure to attend follow-up visits at the doctor so that the treatment progress can be monitored. The doctor will periodically measure blood pressure, height, weight and perform blood tests to prevent side effects.

If your child is not growing in height or gaining weight as expected, breaks in the Ritalin treatment may be necessary.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or pharmacist.

Some medicines and Ritalin that are taken together may interfere with each other. These medicines include:

- medicines that increase blood pressure
- alpha-2 receptor agonists like clonidine (used to treat high blood pressure)
- oral anticoagulants or warfarin (medicines used to prevent blood clots)
- certain anticonvulsants (to treat epilepsy or fits)
- medicines to treat depression, such as tricyclic antidepressants and monoamine oxidase (MAO) inhibitors
- phenylbutazone (to treat pain or fever)
- guanethidine
- anesthetics

- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis)
- medicines that raise the serotonin level in the body (serotonergic medicines, e.g., those used to treat depression, such as sertraline and venlafaxine)

It may be necessary to change the dosage of your medicines or you may have to take other medicines. Consult the doctor.

If you did not inform the doctor of the other medicines you are taking, consult him before taking Ritalin.

If you are about to begin treatment with a new medicine, remind your doctor and pharmacist that you are being treated with Ritalin. Tell every doctor, dentist or pharmacist treating you that you are taking Ritalin.

Use of the medicine and food

The tablets may be taken with or without food (e.g., at breakfast or lunch).

Use of the medicine and alcohol consumption

Do not drink alcohol during the course of treatment with Ritalin. Remember that certain foods and medicines contain alcohol.

Alcohol may exacerbate some of the side effects of Ritalin, such as dizziness and drowsiness.

Pregnancy and breast-feeding

Inform the doctor if you are pregnant or breast-feeding. Ask the doctor about the risks and benefits of taking Ritalin in this case. Do not use Ritalin during pregnancy unless the doctor explicitly prescribed it. This medicine may affect the unborn baby if you take it during pregnancy.

If you became pregnant while being treated with Ritalin, consult the doctor. The doctor will discuss with you the risks and benefits of taking the medicine during pregnancy. Do not breast-feed during the course of treatment with Ritalin. The active ingredient in Ritalin can pass into breast milk.

Driving and using machines

Exercise caution when driving, operating machines or performing activities that require alertness during the course of treatment with Ritalin, until you know how this medicine affects you.

This medicine may cause hallucinations, dizziness, drowsiness, blurred vision or other central nervous system side effects that can impair some people's ability to concentrate. If you experience these symptoms, do not drive a car, operate machines or perform activities that require rapid reactions or that may be dangerous. Children should be cautioned against riding bicycles or playing near the street, etc.

Important information regarding some of the ingredients of the medicine

The medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

The medicine contains wheat starch. This medicine contains only very low levels of gluten (from wheat starch). It is very unlikely to cause problems if you have celiac disease. If you have wheat allergy (different from celiac disease) you should not take this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

Dosage:

The dosage and treatment regimen will be determined by the doctor only, according to the patient's needs and response to treatment.

Do not change the dosage without consulting the doctor.

If you think that the effect of the medicine is too strong or too weak, consult the attending doctor.

Do not exceed the recommended dose.

Duration of treatment:

Continue taking Ritalin for the duration of time instructed by the doctor.

This medicine helps regulate the symptoms, but does not cure. The doctor will check the improvement in the condition in order to confirm that the medicine is working properly and discuss with you the question of how long to continue treatment.

If you are uncertain, talk to the doctor.

Treatment for ADHD varies in length from patient to patient. During the course of treatment of ADHD, the doctor may tell you to stop taking Ritalin for certain periods of time (e.g., over weekends or school vacations and in long vacations) to see if it is still necessary to take it. These treatment breaks also help to prevent a slow-down in growth that sometimes occurs when children take this medicine for a long time.

Method of administration:

The tablets may be taken with or without food.

Take the medicine once or twice a day (for instance, at breakfast and/or at lunch, i.e., split the daily dosage over morning and noon administrations).

Swallow the tablet with a full glass of water.

The tablets can be halved.

If the dose is half a tablet, use the score line to cut the tablet. A tablet splitter can be used to assure the exact dose.

There is no information regarding crushing or chewing the tablets.

If the tablets cause you abdominal discomfort, they can be taken with food, but make sure to always take them the same way (i.e., always with food or always without food). In this way, the effect will always be the same.

In some patients, Ritalin may cause sleeplessness. Consult the doctor regarding the right time during the day to take the last dose of Ritalin.

If you accidentally took a higher dosage

Some of the symptoms of overdose are: vomiting, agitation, headache, tremors, muscle twitching, irregular heartbeat, flushing, fever, sweating, dilated pupils, breathing difficulties, confusion, seizures and muscle spasms accompanied by fever and red-brown urine.

If you took an overdose, or if a child accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine at the designated time, take a dose as soon as you remember and maintain the regular intervals between the doses for that day. For example, if you usually have a 4-hour interval between doses, wait 4 hours before taking the next dose, and so forth, for the rest of that day. On the following day, return to the regular dosing schedule. Do not take two doses together to compensate for the missed dose. If you do so, you may increase the chances of side effects.

If it is hard for you to remember when to take your medicine, consult the pharmacist.

Adhere to the treatment as recommended by the doctor.

As with all stimulants, **this medicine can be addictive and abused by certain people.** If you take it properly, as instructed by the doctor, abuse or dependence should not be a problem, either now or in the future.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. If you stop treatment suddenly, your medical condition may return to its pretreatment state or side effects, such as depression, may occur. In order to avoid this, the doctor may tell you to reduce the daily dose gradually before stopping treatment completely. Medical supervision after stopping treatment is necessary.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ritalin may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Report to the doctor immediately or proceed to an emergency room in the following cases:

- signs of allergy, such as swelling of the face, lips or tongue, shortness of breath, wheezing or breathing difficulties. These are signs of a severe allergic reaction
- weakness or paralysis of the limbs or face, difficulty speaking or unexplained fainting
- skin rash, itching, red blotches on the skin, blisters or peeling of the skin
- sudden increase in body temperature, sweating, fast heartbeat, chest pain, muscle stiffness and blood pressure fluctuations, which may lead to coma
- constant "flu-like" symptoms such as chills, fever, sore throat and runny nose, swollen glands, aching muscles or joints
- unusual bleeding or skin bruising
- unusual tiredness, shortness of breath when exercising, dizziness, pale skin
- involuntary shaking of the body (signs of tremor) such as uncontrollable twitching, jerking or writhing movements
- seizures (fits) or unexplained fainting
- pain or tightness in the chest
- fast or irregular heartbeat
- yellowing of the skin or eyes, dark-colored urine or light-colored bowel motions
- confusion, delusions or hallucinations (seeing or feeling things that are not really there)
- excitement, hyperactivity and uninhibited behavior
- severe or persistent headache
- uncontrolled speech and body movements (Tourette's syndrome)
- prolonged erection causing discomfort of the penis (sign of priapism)
- thoughts or attempts of killing yourself (suicidal ideation or attempt, including completed suicide)
- fingers and toes feeling numb, feeling cold, tingling and changing color (from white to blue, and then red) when cold (Raynaud's phenomenon, peripheral coldness)

The side effects listed above may be serious. Urgent medical supervision may be necessary.

Additional side effects:

Tell the doctor if you notice any of the following effects and it worries you:

Very common side effects - effects that occur in more than 1 in 10 users:

- nausea
- loss of appetite
- sore throat and runny nose
- nervousness
- inability to sleep
- dry mouth

Common side effects - effects that occur in 1-10 in 100 users:

- vomiting or abdominal pain
- upset stomach or indigestion
- feeling nervous, anxious or agitated
- feeling jittery
- restlessness
- sleep disorders
- headache
- cough
- drowsiness
- dizziness
- irritability
- hair loss
- hives (urticaria)
- joint pain
- toothache
- excessive sweating
- abnormal heart rate
- palpitations
- excessive emotional distress or excitement
- decreased weight
- feeling depressed
- feeling aggressive
- excessive teeth grinding

Uncommon side effects - effects that occur in 1-10 in 1,000 users:

- trismus - spasm of the jaw muscles that makes it difficult to open the mouth

Rare side effects - effects that occur in 1-10 in 10,000 users:

- weight loss and slowed growth in children
- blurred vision or visual focus disturbances

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- transient depressed mood
- muscle cramps
- anemia (a reduction in the number of red blood cells), leukopenia (a reduction in the number of white blood cells), thrombocytopenia (a reduction in the number of platelets)
- inflammation of the nasal passages and throat
- swelling of the ears (a sign of an allergic reaction)
- irritability, aggression, mood changes, abnormal behavior or thinking, anger, excessive awareness of surroundings,

feeling unusually excited, over-active and uninhibited (mania), disorientation, changes in sex drive, lack of feeling or emotion, doing things over and over again, being obsessed with one thing, confusion, addiction

- temporary muscle weakness, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischemic neurological deficit), migraine
- double vision, dilated pupils, trouble seeing
- stopped heartbeat, heart attack
- sore throat, shortness of breath
- diarrhea, constipation
- swelling of the face and throat, redness of the skin, large red blotches on the skin appearing a few hours after taking the medicine
- muscle pain, muscle twitching
- blood in the urine
- swelling of the breasts in men
- chest pain, tiredness, sudden death
- abnormal sounds from the heart

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C. Store in the original packaging in order to protect from moisture.
- Do not use if the package is damaged or shows signs of tampering.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains: Wheat starch, lactose cryst., calcium phosphate tribasic, talc, gelatin, magnesium stearate

Each tablet contains 40 mg lactose and 48 mg wheat starch (contains gluten).

What the medicine looks like and the contents of the package:

The medicine is marketed in tablet form. The tablets are white, round, flat with beveled edges, with "CG" stamped on one side and "A/B" and a score line on the other side and may contain dark specks.

The package contains 30 tablets.

Registration Holder and Importer and its address:

Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113 76 22498

Revised in April 2022 according to MOH guidelines.