

Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Rephenidate® 10 mg, Tablets

Each tablet contains Methylphenidate Hydrochloride 10 mg

Inactive ingredients and allergens in the medicine – see section 6 "Additional information".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

Abuse, misuse and addiction

When using **Rephenidate 10 mg** there is a high chance for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Abuse and misuse in substances which stimulants the central nervous system, including **Rephenidate 10 mg**, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

1. What is the medicine intended for?

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

Therapeutic group: Central nervous system stimulant.

Rephenidate 10 mg 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, in adolescents, and in 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 become bored easily. They may experience difficulty organizing their private life and work.

Methylphenidate is assumed to work by regulating specific chemicals in the brain that affect behavior. It helps to focus attention, shuts out distraction and allows impulsive people to think before they act. If the 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 usual state of fatigue. Patients with narcolepsy experience recurring and irresistible attacks of sleep during the day in spite of having enough sleep at night. Narcolepsy must be diagnosed by a doctor by recording wake-sleep patterns.

Rephenidate 10 mg 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 **Rephenidate 10 mg** 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 the medicine:

- If you are hypersensitive (allergic) to the active ingredient (Methylphenidate) or to any of the other ingredients this medicine contains (see section 6). Some of the symptoms of an 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 Rephenidate 10 mg 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 pectoris), heart failure, heart disease or congenital heart problem
- very high blood pressure (hypertension) or narrowing of the arterial blood vessels (arterial occlusive disease, that may 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 Rephenidate 10 mg 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 Rephenidate 10 mg treatment (see section "Drug interactions").

Taking **Rephenidate 10 mg** 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 the 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.

Abuse, misuse and addiction

When using **Rephenidate 10 mg** there is a high chance for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Abuse and misuse in **Rephenidate 10 mg**, in other medicines which contain methylphenidate, and in medicines which contain amphetamine, can result in overdose and death. The risk for overdose and death increases with higher doses of **Rephenidate 10 mg** or while using **Rephenidate 10 mg** in unapproved methods of administration, such as snorting or injection.

- The doctor must check your or your child's risk of abuse, misuse and addiction before starting treatment with **Rephenidate 10 mg** and he will monitor you or your child during the treatment.
- **Rephenidate 10 mg** may lead to a physical dependence after prolonged use, even if it was taken according to the doctor's instructions.
- Do not give **Rephenidate 10 mg** to anyone else: **Methylphenidate may be used as a target for people who abuse prescription medicines or street drugs.** Store the medicine in a safe place to protect it from theft. Never give your medicine to anyone else because it could cause death or harm them. Selling or giving **Rephenidate 10 mg** to others may harm them and is against the law.

- Store the medicine in a safe place and properly throw away any unused medicine (see section 5 "How to store the medicine?").
- Tell your doctor if you or your child have ever abused or developed a dependence on alcohol, prescription medicines or street drugs.

Before treatment with Rephenidate 10 mg, 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 blood vessel (aneurysm), stroke or inflammation of blood vessels (vasculitis)
- severe depression, bipolar disorder or other mental illnesses
- epilepsy (seizures, convulsions or fits)
- high blood pressure
- 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 suffer from these conditions
- psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- aggressive behavior
- suicidal behavior or thoughts
- have or develop eye problems, including increased pressure in your eye, glaucoma or problems with your close-up vision (farsightedness)

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

Additional warnings

- **Rephenidate 10 mg** may give a false-positive result in tests for drug use, including tests used in sports.
- Some children receiving **Rephenidate 10 mg** for a long time may have a slowdown 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, **Rephenidate 10 mg** may cause abdominal discomfort, loss of appetite and sleeping difficulties, especially at the beginning of treatment. The doctor can help reduce these symptoms by lowering the dose of **Rephenidate 10 mg** or by changing the dosing times of the medicine.
- If during **Rephenidate 10 mg** treatment or after treatment discontinuation, you experience abnormally sustained or frequent and painful erections of the penis, 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 **Rephenidate 10 mg** with medicines that raise the serotonin level in the body (serotonergic medicines, such as 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 **Rephenidate 10 mg** and these medicines and refer to your doctor immediately.
- If you are about to undergo an operation, inform the doctor that you are taking **Rephenidate 10 mg**. Do not take **Rephenidate 10 mg** 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 6 years of age.

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 **Rephenidate 10 mg** treatment may be necessary.

Drug interactions

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

Some medicines and **Rephenidate 10 mg** 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. See also section "Do not use this medicine"
- 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 serotonin level in the body (serotonergic medicines, e.g., those used to treat depression, like 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 **Rephenidate 10 mg**.

If you are about to begin treatment with a new medicine, remind your doctor and pharmacist that you are being treated with **Rephenidate 10 mg**.

Tell every doctor, dentist or pharmacist treating you that you are taking **Rephenidate 10 mg**.

Use of the medicine and food

Rephenidate 10 mg 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 **Rephenidate 10 mg**. Remember that certain foods and medicines contain alcohol.

Alcohol may exacerbate some of the side effects of **Rephenidate 10 mg**, such as dizziness and drowsiness.

Pregnancy and Breastfeeding

Inform the doctor if you are pregnant or breastfeeding. Ask the doctor about the risks and benefits of taking **Rephenidate 10 mg** in this case. Do not use **Rephenidate 10 mg** 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 **Rephenidate 10 mg**, consult the doctor. The doctor will discuss with you the risks and benefit of taking the medicine during pregnancy.

Do not breastfeed during the course of treatment with **Rephenidate 10 mg**. The active ingredient in **Rephenidate 10 mg** 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 **Rephenidate 10 mg**, 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 may 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.

As for children, they should be warned about riding a bicycle or playing near roads etc.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

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.

When and how to take Rephenidate 10 mg

Rephenidate 10 mg can be taken with or without food.

Take **Rephenidate 10 mg** once or twice a day (for instance, at breakfast and/or at lunch, i.e., split the daily dosage over morning and noon administration).

Swallow the tablet with a full glass of water. If necessary, the tablet can be split in half for immediate use, only to ease swallowing. Swallow both halves together immediately after splitting. There is no data regarding chewing/ crushing.

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

In some patients, **Rephenidate 10 mg** may cause sleeplessness. Consult the doctor regarding the right time during the day to take the last dose of **Rephenidate 10 mg**.

Duration of treatment

Continue taking **Rephenidate 10 mg** 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 duration of treatment with this medicine. **If you are not sure, 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 **Rephenidate 10 mg** 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 slowdown in growth that sometimes occurs when children take this medicine for a long time.

If you have accidentally taken a higher dosage

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

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 forgot to take the medicine

If you forgot to take this 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.

Continue with the treatment as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment without consulting the doctor. If you stop the 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 the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Rephenidate 10 mg** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

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

- signs of an allergy, such as swelling of the face and throat, 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 fluctuations blood pressure, 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 suicide actual)
- fingers and toes feeling numb, feeling cold, tingling and changing color (from white to blue, and then red) upon exposure to cold (Raynaud's phenomenon, peripheral coldness)
- uncontrollable twitching and jerking (dyskinesia)

- an abnormal decrease in the level of blood cells of all types. It is associated with anemia, a decrease in platelets and a decrease in white blood cells. This can lead to fatigue, increased risk of bleeding and/or increased risk of infection. This may be serious or life-threatening (Pancytopenia)

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 out of 100 users):

- vomiting or abdominal pain
- upset stomach or indigestion
- feeling 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 out of 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 out of 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):

- depressed mood, transient
- 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)

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- stuttering
- bed wetting in children at night
- chest pain, tiredness
- inability to develop or maintain an erection, swelling of the breasts in men
- 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, change 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
- redness of the skin, large red blotches on the skin appearing a few hours after taking the medicine
- muscle pain, muscle twitching
- increased pressure in the eye

Additional side effects that occurred with other medicines that contain the same active ingredient as **Rephenidate 10 mg**:

- blood in the urine
- sudden death
- abnormal sounds from the heart

If a side effect appears, 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

"דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website

(www.health.gov.il) directing to the online form reporting side effects or via the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- **Avoid poisoning!** This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXPIRY DATE) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C. Store in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Calcium hydrogen phosphate dihydrate, microcrystalline cellulose, maize starch, magnesium stearate.

What the medicine looks like and what the package contains:

A white, round and flat tablet with a score line marked "RU 10" on one side.

Approved package size: 30 tablets.

Manufacturer and address: Laboratorios Rubio S.A., Barcelona, Spain

Revised in July 2024 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

157-18-34355-00

Registration holder: Dexcel Ltd., 1 Dexcel Street, Or Akiva 3060000, Israel