

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Phenidin 18 mg Prolonged-release tablets	Phenidin 27 mg Prolonged-release tablets
Active ingredient	Active ingredient
Each tablet contains:	Each tablet contains:
18 mg methylphenidate hydrochloride	27 mg methylphenidate hydrochloride
Phenidin 36 mg Prolonged-release tablets	Phenidin 54 mg Prolonged-release tablets
Active ingredient	Active ingredient
Each tablet contains:	Each tablet contains:
36 mg methylphenidate hydrochloride	54 mg methylphenidate hydrochloride

Inactive ingredients and allergens in this medicine – see section 2 under 'Important information about some of this medicine's ingredients', and section 6, 'Additional information'.

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

WARNING: ABUSE, MISUSE, AND ADDICTION
There is a high risk of abuse and misuse with Phenidin, which can lead to the development of substance abuse, including addiction. Abuse and misuse of medicines that stimulate the central nervous system, including Phenidin, can lead to overdose and death (see under 'If you accidentally take a higher dose'). This risk increases with higher doses or when taking by an unapproved route such as snorting or injection.

1. What is this medicine intended for?

Phenidin is intended for the treatment of attention deficit hyperactivity disorder (ADHD) in children over the age of 6, adolescents, and adults up to the age of 65. Phenidin can improve attention and concentration, and reduce impulsiveness and hyperactivity in people with ADHD. Phenidin should be given as part of a treatment program for ADHD, which may include counseling or other therapies.

Therapeutic group: central nervous system stimulant.

2. Before using this medicine

Do not use this medicine if you or your child:

- is sensitive (allergic) to the active ingredient (methylphenidate hydrochloride) or to any of the other ingredients in this medicine (see section 6 – 'Additional information')
- has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are uncontrolled repeated movements or sounds.
- is currently taking or has taken within 14 days before starting Phenidin treatment an antidepressant that belongs to the monoamine oxidase inhibitor (MAOI) group
- Do not use Phenidin in children under the age of 6, because it has not been studied in this age group.

Special warnings about using this medicine

Before starting treatment with Phenidin, tell your doctor if you or your child has ever had, or has a family history of, any of the following conditions:

- alcohol, prescription drug, or street drug addiction/dependence or abuse.
- heart problems, heart disease, heart defect, or high blood pressure.
- a family history of sudden death.
- mental problems, such as psychosis, mania, bipolar disorder or depression, or a family history of suicidality, bipolar disorder or depression.
- uncontrolled, repetitive movements or sounds (tics) or Tourette's syndrome, or a family history of tics or Tourette's syndrome.
- seizures or abnormal brain scan (EEG) results.
- circulation (blood flow) problems in fingers and toes.
- digestive system problems – obstruction or narrowing of the intestines.
- eye problems including intraocular pressure and glaucoma, or problems seeing near things (far-sightedness).

The following problems were reported with use of methylphenidate hydrochloride and other stimulants:

Abuse, misuse and addiction

There is a high risk of abuse with Phenidin, which can lead to problems when taking this medicine, including addiction. Abuse of Phenidin, other medicines that contain methylphenidate, and medicines that contain amphetamine, may lead to overdose and death. The risk of an overdose and death increases when taking higher doses of Phenidin or when taking it in an unapproved way, such as snorting or injection.

- Your doctor should check you or your child's risk of abuse, misuse, and addiction before starting treatment with Phenidin, and monitor your or your child's treatment.
- Phenidin may lead to physical dependence after prolonged use, even if taken as directed by your doctor.
- Do not give Phenidin to anyone else. See section 1 'What is this medicine intended for?' for more information.
- Keep this medicine in a safe place and dispose of any remaining medicine. See section 5 'How to store the medicine?'.
- Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Heart-related problems

- sudden death in patients who have heart problems or a heart defect.
- stroke and heart attacks in adults.
- increased blood pressure and heart rate.

In general, Phenidin should not be used in children, adolescents, or adults who have a heart defect or other serious heart problems.

Contact a doctor immediately or go to the nearest hospital emergency room if you or your child develops symptoms of heart problems such as chest pain, shortness of breath, or fainting while using Phenidin.

Increased blood pressure and heart rate

Stimulants may cause an increase in blood pressure and heart rate. If you are taking medicines to treat high blood pressure and increased heart rate, your doctor will monitor your blood pressure and heart rate measurements.

Mental (psychiatric) problems

- stimulants can cause behavioral or thought problems or make these worse in patients with an existing mental problem.
- onset or worsening of bipolar disorder.
- new psychotic effects (such as hearing voices or seeing things that do not exist) or onset of new manic symptoms.

Tell your doctor about any mental problems, family history of suicide, bipolar disease or depression that your or your child has.

Refer to a doctor immediately if you or your child experiences new or worsening mental symptoms or problems while using Phenidin, especially hearing voices and seeing things that are not real, believing in things that are not real, or onset of new symptoms of mania.

Children and adolescents

Do not use Phenidin in children under the age of 6, because this medicine has not been studied in this age group.

Tests and follow-up

Before starting treatment with Phenidin, your doctor will check you or your child for heart problems.

The doctor will regularly monitor your or your child's blood tests, blood pressure, and heart rate during treatment with Phenidin.

The height and weight of children taking Phenidin should be monitored frequently.

Phenidin treatment may be stopped if a problem is found during these check-ups.

Interactions with other medicines

If you or your child is taking or has recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Phenidin in combination with certain medicines may cause serious side effects. It is sometimes necessary to adjust the dosages of these medicines while taking Phenidin. Your doctor will decide whether Phenidin can be taken with other medicines.

Especially, tell your doctor or pharmacist if you or your child is taking any of the following:

- monoamine oxidase inhibitors (MAOIs). Do not take Phenidin if you or your child is taking, or has taken within 14 days before starting treatment with Phenidin, medicines for depression that belong to the MAOI group (also see section 2 under 'Do not use this medicine').
 - medicines for blood pressure.
 - medicines that affect blood vessel constriction (such as cold or allergy medicines that contain decongestants).
 - anticoagulants that belong to the coumarin group (such as warfarin).
 - medicines for seizures (such as phenobarbital, phenytoin, primidone).
 - medicines for depression (such as tricyclic antidepressants and serotonin reuptake inhibitors).
 - a medicine for mental illness – risperidone.
- Know the medicines that you or your child takes. Keep a list of your or your child's medicines to show your doctor and your pharmacist when you get a new medicine.

Do not start taking new medicines while taking Phenidin without talking to your doctor first.

If you are going to have surgery

Tell your doctor if you are going to have surgery. This is because you must not take methylphenidate on the day of your surgery with a certain type of anesthetic. There is a risk of a rise in blood pressure during surgery.

Using this medicine and food

Swallow the tablet whole with water or another liquid.

The tablet can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant, breastfeeding, or planning to become pregnant, tell your doctor who will decide if you can take Phenidin.

Pregnancy

It is unknown whether Phenidin can harm an unborn baby.

Breastfeeding

It is unknown whether Phenidin passes into breastmilk. Consult your doctor about the best way to feed your baby while you are taking Phenidin.

Driving and using machines

Stimulant substances can impair your or your child's ability to operate dangerous machines or drive.

Exercise caution, and only perform these activities if you or your child is sure that the medicine does not affect the ability to drive or operate dangerous machines.

Important information about some of this medicine's ingredients

Phenidin contains sucrose. Consult your doctor before starting this medicine if you have an intolerance to certain sugars.

This medicine contains less than 1 millimole (23 mg) sodium per tablet, which means it is considered essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

Phenidin is an prolonged-release tablet. It releases the medicine into the body throughout the day.

Phenidin 18 mg - Swallow the tablet whole; do not chew, split or crush the tablet.

Phenidin 27 mg, 36 mg, 54 mg- You may split the tablet. Do not chew or crush the tablet.

Swallow the tablet with water or another liquid.

The tablet can be taken with or without food.

Take the tablet once a day, in the morning.

Your doctor may occasionally stop Phenidin treatment for a while to check ADHD symptoms.

If you accidentally take a higher dose, side effects may occur as a result of overdose:

- Effects on heart and blood pressure: changes in and disturbed heart rhythm, high or low blood pressure.
- Effects on the central nervous system: agitation and increased uncontrolled movements, feeling of confusion, hallucinations (seeing, feeling and hearing things that are not real); serotonin syndrome, seizures, stroke, and coma.
- life-threatening high fever and muscle breakdown (rhabdomyolysis).

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

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Consult your doctor before you stop using this medicine.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Phenidin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Phenidin may cause serious side effects. Consult your doctor immediately in the following situations:

- Abuse, misuse and addiction** (see section 2 'Before using this medicine')
- Signs of allergy** such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing.
- Symptoms of heart problems** such as chest pain, shortness of breath or fainting. The following side effects have been reported with methylphenidate or other stimulants: sudden death in patients who have heart problems or a heart defect; stroke and heart attacks in adults; increased blood pressure and heart rate.
- Increased blood pressure and heart rate.** Stimulants may cause an increase in blood pressure and heart rate. If you are taking medicines to treat high blood pressure and increased heart rate, your doctor will monitor blood pressure and heart rate measurements.
- Mental (psychiatric) problems.** New or worsening mental symptoms or mental problems while taking Phenidin, especially, seeing and hearing things that are not real, believing things that are not real or are suspicious; behavior or thinking problems; depression; bipolar disorder (see section 2 'Before using this medicine').
- Seizures.** If you or your child develops seizures, your doctor will instruct you to stop the treatment.
- Prolonged and painful erection (priapism).** There have been cases of priapism that required surgery in patients treated with methylphenidate. **If you or your child develops priapism, get medical assistance immediately.**
- Circulation problems in the fingers and toes** (peripheral vasculopathy), including Raynaud's phenomenon. Symptoms may include:
 - numbness, chilly or painful fingers or toes.
 - skin color of fingers or toes changes from pale to blue and red.
Consult your doctor if you or your child has numbness, pain, change in skin color, or sensitivity to temperature in fingers or toes.
- Consult your doctor immediately if you or your child develops signs of unexplained sores in the fingers or toes while taking Phenidin.**
- Slowed growth (height and weight) in children.** Children's height and weight should be checked frequently during Phenidin treatment. If your child is not growing or gaining weight as expected, their treatment may need to be stopped.
- Blockage of the intestine may occur.** Phenidin is not intended for people with serious intestinal problems (severe narrowing of the intestine).
- Eye problems (increased intraocular pressure and glaucoma).** Contact your doctor immediately, if you or your child develops vision changes or pain, swelling or redness in the eyes.
- Changes in vision or blurred vision.**
- Onset of or worsening tics or worsening Tourette's syndrome.** Tell your doctor immediately if you or your child has new or worsening tics, or worsening Tourette's syndrome while taking Phenidin.

Additional side effects

Very common side effects:

In children:

- upper abdominal pain

In adults:

- decreased appetite
- headache
- dry mouth
- nausea
- insomnia
- anxiety
- dizziness
- weight loss
- nervousness
- increased sweating

Common side effects observed in clinical trials:

In children and adolescents: upper abdominal pain, vomiting, fever, inflammation of the mucosa of the nose and pharynx with suppurating nasal discharge (nasopharyngitis), dizziness, insomnia, cough, pain in the mouth and pharynx.

In adults: rapid pulse, palpitations, vertigo (spinning sensation), blurred vision, dry mouth, nausea, indigestion, vomiting, constipation, irritability, upper respiratory tract infection, weight loss, reduced appetite, anorexia (eating disorder), muscle tension, headache, dizziness, tremor, tingling (paresthesia), sedation, tension headache, insomnia, anxiety, primary insomnia, depressed mood and depression, nervousness, restlessness, aggression, teeth grinding, decreased libido, emotional instability, feeling confused, tension, pain in the mouth and pharynx, excessive sweating.

Additional side effects that have been reported in clinical trials:

low white blood cell count (leukopenia), dry eyes, impaired accommodation (focusing), hot flushes, abdominal discomfort or pain, diarrhea, weakness, fatigue, feeling tense/nervous, feeling thirsty, sinusitis, increased level of the alanine aminotransferase enzyme, increased heart rate and blood pressure, heart murmur, muscle spasms, lethargy, sleepiness, psychomotor hyperactivity, anger, excessive alertness, mood swings, frequent fluctuations in mood, panic attack, sleep disorder, tendency to cry, tics, impotence, shortness of breath, skin rash, macular rash, high blood pressure.

Additional side effects reported after the product was marketed:

pancytopenia (very low count of all blood cell types – red, white, and platelets), reduced platelet count (thrombocytopenia), thrombocytopenic purpura (bleeding characteristic of a very low platelet count).

angina pectoris, slow heart rate, heart rhythm disturbances.

double vision, increased intraocular pressure, dilated pupils, vision problems. chest pain, chest discomfort, reduced effect or response to the medicine, high fever.

liver cell damage, acute liver failure.

hypersensitivity reaction (allergy) such as: angioedema, anaphylactic reaction, swelling of the ear, blisters on the skin, peeling of the skin, hives (a skin disease), itching, skin irritation and/or skin infection, rash.

increased blood level of the alkaline phosphatase enzyme, increased blood level of bilirubin, increased blood level of liver enzymes, abnormal white blood cell and platelet counts.

joint pain, muscle pain, muscle spasms, muscle breakdown (rhabdomyolysis). seizures, dyskinesia (repeated involuntary movements), serotonin syndrome (when combined with certain other medicines), motor and verbal tics.

feeling disorientated, hallucinations (visual or auditory), mania, excessive talking, libido changes, prolonged and painful erection (priapism), hair loss in different parts of the body (alopecia), skin redness (erythema), constriction of the blood vessels in the tips of the fingers and toes, usually after exposure to cold (Raynaud's syndrome).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>
You can also report side effect by email at safety@trima.co.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Store this medicine in a safe place such as a locked room.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Store below 25°C. Close the bottle tightly.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Tablet core: sugar spheres (sucrose, maize starch), hypromellose, talc, ethylcellulose, hydroxypropylcellulose, triethyl citrate, hypromellose acetate succinate, carmellose sodium, cellulose microcrystalline, magnesium stearate, silica colloidal anhydrous, hydrochloric acid (pH adjustment).

Tablet coating:

18 mg: polyvinyl alcohol, talc, titanium dioxide, iron oxide yellow, macrogol 3350.

27 mg: polyvinyl alcohol, talc, iron oxide yellow, macrogol 3350.

36 mg: polyvinyl alcohol, talc, titanium dioxide, macrogol 3350.

54 mg: polyvinyl alcohol, talc, titanium dioxide, macrogol 3350, iron oxide red.

What the medicine looks like and contents of the pack:

Phenidin 18 mg: round, yellowish to yellow film-coated tablet.

Phenidin 27 mg: elongated, yellow film-coated tablet, with a score line on both sides.

Phenidin 36 mg: elongated, white to off-white film-coated tablet, with a score line on both sides.

Phenidin 54 mg: elongated, reddish-red film-coated tablet, with a score line on both sides.

Each pack contains 30 tablets in a child-resistant bottle.

Registration holder's name and address: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.

Manufacturer's name and address:

Develco Pharma GmbH, Griennatt 27, 79650 Schopfheim, Germany.

Revised in August 2024.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:

Phenidin 18 mg: 161-08-35114-00

Phenidin 27 mg: 161-09-35115-00

Phenidin 36 mg: 161-10-35116-00

Phenidin 54 mg: 161-11-35117-00