

**Patient leaflet in accordance with the Pharmacists’ Regulations (Preparations) - 1986**

This medicine is dispensed with a doctor’s prescription only

## Phenidin prolonged-release tablets

**Each Phenidin 18 mg tablet contains: methylphenidate hydrochloride 18 mg. Each Phenidin 27 mg tablet contains: methylphenidate hydrochloride 27 mg. Each Phenidin 36 mg tablet contains: methylphenidate hydrochloride 36 mg. Each Phenidin 54 mg tablet contains: methylphenidate hydrochloride 54 mg.**

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 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 to yours.

### 1. What is this medicine intended for?

Phenidin is intended for the treatment of attention deficit hyperactivity disorder (ADHD) in children over 6 years old, adolescents, and adults up to 65 years old.

Phenidin can improve attention and concentration and reduce impulsivity and hyperactivity in people with ADHD. Phenidin should be given as part of an ADHD treatment program that may include counselling or other therapy.

**Therapeutic group:** central nervous system stimulant.

### 2. Before using this medicine

<p><b>Do not use this medicine if:</b></p> <ul style="list-style-type: none"><li>• you are sensitive (allergic) to the active ingredient (methylphenidate hydrochloride) or to any of the other ingredients in this medicine (see section 6 ‘Additional information’)</li><li>• you are experiencing marked anxiety, mental tension, or agitation</li><li>• you have an eye problem called glaucoma (increased intraocular pressure)</li><li>• you have tics or Tourette’s syndrome, or a family history of Tourette’s syndrome. Tics are repetitive movements or sounds that you cannot control.</li><li>• you are taking a medicine for depression that belongs to a group called monoamine oxidase inhibitors (MAOI) or have taken such a medicine during the 14 days before starting treatment with Phenidin</li><li>• Do not use Phenidin in children under 6 years old as this medicine has not been studied in this age group.</li></ul>
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#### Special warnings about using this medicine:

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

- heart function problems, heart defects, or high blood pressure.
- a family history of sudden death.
- mental health problems such as psychosis, mania, bipolar disorder, or depression.
- a family history of suicide.
- tics or Tourette’s syndrome.
- seizures or abnormal results of a brain scan (EEG).
- circulation (blood flow) problems in fingers and toes.
- digestive system problems – esophagus, stomach, or intestine (small or large intestine).
- addiction/dependence or abuse of alcohol, prescription medicines, or street drugs.

**The following problems have been reported with use of methylphenidate hydrochloride and other stimulants:**

#### Heart 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.

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

Consult your doctor immediately if you or your child experiences symptoms of heart problems such as chest pain, shortness of breath or fainting while using Phenidin.

#### Mental health (psychiatric) problems:

In all patients: Onset or worsening of the following problems: behavioral or thought problems, bipolar disorder, aggressive or hostile behavior.

In children and adolescents: onset of psychotic symptoms (such as hearing voices, believing in things that are either not real or are suspicious) or manic symptoms.

Consult a doctor immediately if you or your child experiences new onset or worsening of mental symptoms or problems during treatment with Phenidin, especially seeing and hearing things that are not real, believing in things that are not real or are suspicious.

#### Prolonged and painful erections (priapism)

Prolonged and painful erections have been reported with use of methylphenidate. Consult a doctor immediately if you or your child experiences this effect as there is potential for irreversible damage.

**Circulation problems (blood flow) in the fingers and toes (peripheral vasculopathy, including Raynaud’s phenomenon)**

- Fingers or toes may feel cold and painful or numb.
  - Fingers or toes can change color from pale to blue, to red.
- Tell your doctor if you notice numbness, pain, skin color change, or sensitivity to temperature in the toes or fingers.

Consult your doctor immediately if you or your child gets signs of bruising on fingers or toes while taking Phenidin.

#### Dependence and addiction

Using this medicine can result in dependence or abuse. To prevent misuse, keep this medicine in a safe place. Selling or giving this medicine to other people can harm them and is against the law.

#### Children and adolescents

Do not use Phenidin in children under 6 years old as this medicine has not been studied in this age group.

#### Tests and follow-up

Your doctor will check you or your child for heart problems before starting Phenidin treatment.

Your doctor will regularly monitor you or your child’s blood tests, blood pressure, and heart rate during the course of treatment with Phenidin. The height and weight of children who are taking Phenidin must be monitored frequently.

Phenidin treatment may be stopped if a problem is found in these measurements.

#### Drug interactions:

**If you or your child is taking or has recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**

In combination with certain medicines, Phenidin can cause serious side effects. In some cases, the dosages of these medicines will need to be adjusted during treatment with Phenidin. Your doctor will decide whether Phenidin can be taken with other medicines.

**Particularly inform your doctor or pharmacist if you or your child is taking any of the following:**

- monoamine oxidase inhibitors (MAOI). Do not take Phenidin if you or your child is taking a medicine for depression that belongs to a group called monoamine oxidase inhibitors (MAOI) or have taken such a medicine during the 14 days before starting treatment with Phenidin (see also section 2 under ‘Do not use this medicine if’).
- medicines for depression such as tricyclic antidepressants and serotonin reuptake inhibitors
- medicines for epilepsy (such as phenobarbital, phenytoin, primidone)
- medicines for blood clots (such as warfarin and others)
- medicines for blood pressure
- medicines for narrowing blood vessels
- cold or allergy medicines that contain decongestants.

Know the medicines you or your child is taking. Show your doctor or pharmacist the list of medicines you or your child is taking.

Do not start taking new medicines during the course of treatment with Phenidin without first talking to your doctor.

#### Using this medicine and food:

Swallow the tablet with water or another liquid. The tablet can be taken with or without food.

#### Pregnancy and breastfeeding:

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

#### Driving and using machines:

Stimulants may impair your ability or your child’s ability to operate dangerous machines or drive. You or your child must be cautious and only perform these activities when certain 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 a source of sucrose. Consult your doctor before you start taking this medicine if you have an intolerance to certain sugars.

### 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 a 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 treatment with Phenidin for a while in order to check the symptoms of ADHD.

**If you have accidentally taken a higher dose,** you might get side effects of overdose: vomiting, agitation, increase in involuntary movements, muscle spasms, convulsions, feeling confused, hallucinations (seeing, feeling, and hearing things that are not real), increased sweating, headache, high fever, heart rhythm changes and disorders, high blood pressure, rhabdomyolysis, dilated pupils, dry mouth.

**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.

**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

Like with all medicines, 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.

#### Consult your doctor immediately if you get any of the following:

- signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.
- symptoms of heart problems such as chest pain, shortness of breath or fainting. The following side effects have been reported with use of methylphenidate and other stimulants: rise in blood pressure and pulse, stroke and heart attacks in adults, sudden death in patients with heart problems or a heart defect.
- mental health (psychiatric) problems: new onset or worsening of mental symptoms or problems during treatment with Phenidin, especially seeing and hearing things that are not real, believing in things that are not real or are suspicious, behavioral or thought problems, depression, bipolar disorder, agitation, muscle twitching, aggressive or hostile behavior.
- mental health (psychiatric) problems in children and in adults: onset of psychotic symptoms (such as hearing voices, believing in things that are either not real or are suspicious) or manic symptoms.
- prolonged and painful erections (priapism). Get checked immediately by a doctor due the possibility of irreversible damage.
- numbness, pain, change in skin color, or sensitivity to temperature, or unexplained sores on the toes or fingers. This may be due to circulation problems in fingers and toes (peripheral vasculopathy including Reynaud’s phenomenon).
- Phenidin may cause growth rate (height and weight) in children to slow down.
- seizures mainly in patients with a history of seizures.
- changes in vision or blurred vision.
- blockage of the esophagus, stomach, small or large intestine, in patients already suffering from narrowing of these organs.

#### Additional side effects:

##### **Very common side effects:**

- reduced appetite
- dry mouth
- insomnia
- dizziness
- abdominal pain
- increased sweating
- headache
- nausea
- anxiety
- weight loss
- irritability

#### **Common side effects observed in clinical trials:**

vomiting, fever, nasopharyngitis (inflammation of the mucosa of the nose and pharynx with suppurative nasal discharge), cough, pharyngeal pain, rapid heart rate, palpitations, vertigo (spinning sensation), blurred vision, indigestion, constipation, upper respiratory tract infection, reduced appetite, anorexia (eating disorder), feeling of muscle tension, tremor, tingling (paresthesia), sedation, tension headache, depressive mood and depression, restlessness, aggression, decreased libido, feeling confused, teeth grinding, tension, emotional instability.

#### **Additional side effects reported in clinical trials:**

low white blood cell count (leukopenia), dry eyes, accommodation (visual focus) disorder, hot flushes, abdominal discomfort, diarrhea, weakness, fatigue, exhaustion, feeling tense/jittery, feeling thirsty, sinusitis, increased levels of the enzyme alanine aminotransferase, heart murmur, muscles spasms, lethargy, sleepiness, psychomotor hyperactivity, anger, increased alertness, altered mood, frequent mood swings, panic attack, trouble sleeping, tearfulness, uncontrollable speech and body movements (Tourette-tics), erectile dysfunction, shortness of breath, skin rash, macular rash, high blood pressure.

#### **Additional side effects reported during use:**

pancytopenia (too low counts of all blood cells – red, white, and platelets), decreased platelet count (thrombocytopenia), thrombocytopenic purpura (bleeding that is characteristic of very low platelet count).

chest angina, slow pulse, heart rhythm disorders, double vision, dilated pupils, vision problems, chest pain, chest discomfort, reduced effect of the medicine or of response to the medicine, high fever, damage to liver cells, severe liver failure.

hypersensitivity (allergy) reaction such as angioedema, anaphylactic shock, swelling of the ear, blisters on the skin, skin peeling, hives (skin condition), itching, skin irritation, lumps and/or skin infection, rash,

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

joint pain, muscle pain, muscle spasms, rhabdomyolysis.

convulsions, dyskinesia (repeated involuntary movements), serotonin syndrome (in combination with certain medicines), disorientation, hallucinations (visual or auditory), mania, excessive talkativeness, changes in libido, prolonged and painful erection (priapism), hair loss in different parts of the body (alopecia), skin redness (erythema), tightening of the blood vessels in the tips of the fingers and toes usually after exposure to cold (Raynaud’s phenomenon).

**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 link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

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

Side effects can also be reported by email at: [safety@trima.co.il](mailto: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 a doctor.
- 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. Keep the bottle tightly closed.

### 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

Each Phenidin 18 mg tablet contains 10.9 mg sucrose.

Each Phenidin 27 mg tablet contains 16.4 mg sucrose.

Each Phenidin 36 mg tablet contains 21.8 mg sucrose.

Each Phenidin 54 mg tablet contains 32.7 mg sucrose.

What the medicine looks like and contents of the pack

Phenidin 18 mg: a round yellowish to yellow tablet. Each package contains 30 tablets.

Phenidin 27 mg: an oblong yellow tablet with a score line on both sides. Each package contains 30 tablets.

Phenidin 36 mg: an oblong white to creamy tablet with a score line on both sides. Each package contains 30 tablets.

Phenidin 54 mg: an oblong reddish to red tablet with a score line on both sides. Each package contains 30 tablets.

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

Manufacturer: Develco Pharma GmbH, Grienmatt 27, 79650 Schopfheim, Germany.

Revised in April 2021 according to MOH guidelines.

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

Phenidin 18 mg: 161-08-35114-00/01

Phenidin 27 mg: 161-09-35115-00/01

Phenidin 36 mg: 161-10-35116-00/01

Phenidin 54 mg: 161-11-35117-00/01