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

The 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 the preparation - see section 6 - "FURTHER INFORMATION".

Read this leaflet carefully in its entirety before using this 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 your treatment. 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?

Phenidin is intended for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children, adolescents and adults up to 65 years of age as part of a treatment program that usually includes psychological, educational and social therapy.

Phenidin can improve the attention and concentration and reduce impulsiveness and hyperactivity in individuals with ADHD.

Therapeutic group: Central nervous system stimulant

## 2. BEFORE USING THE MEDICINE:

#### ■ Do not use the medicine if:

- The medicine is not intended for children under 6 years of age.
- You are sensitive (allergic) to the active ingredient (methylphenidate hydrochloride) or to any of the other ingredients contained in the medicine (see section 6 "FURTHER INFORMATION").
- You suffer from thyroid gland problems.
- You have a tumor of the adrenal gland called pheochromocytoma.
   You have eating problems, when you do not feel hungry or do not want to eat, such as "anorexia nervosa".
- You have very high blood pressure or narrowing of the blood vessels, that may cause pains in the arms and legs.
- You are suffering, or have suffered in the past, from heart problems, such as heart attack, irregular heart rate, pains and discomfort in the chest (angina), heart failure, heart disease or a congenital heart problem.
- You are suffering, or have suffered in the past, from cerebrovascular problems, such as a stroke, swelling or weakening of blood vessels (cerebral aneurysm), narrowing or blockage of blood vessels, or inflammation of the blood vessels (vasculitis).
- You suffer from severe anxieties or mental stress, as the treatment with this medicine may worsen them.
- You suffer from mental problems, such as schizophrenia, psychoses, severe mood disturbances, such as depression, mania, suicidal thoughts.
- You suffer or you know of a family history of Tourette's Syndrome, manifested by recurrent, uncontrollable twitching in different parts of the body, and/or lack of control of any repetitive verbalizations.
- You suffer from increased intraocular pressure (glaucoma).
- You are currently taking or if you have taken within 14 days before starting treatment with Phenidin, preparations for the treatment of depression from the monoamine oxidase inhibitors (MAOI) group. Do not take or give Phenidin to your child if any of the describedabove effects apply to you or your child. If you are not sure, refer to the doctor or pharmacist before taking the medicine. This is because Phenidin can make these problems worse.

## ■ Special warnings regarding the use of the medicine:

- Prolonged, unregulated use may cause dependence and psychotic effects; therefore, do not use the medicine frequently or for a prolonged period without consulting the doctor.
- Use of this medicine may cause blurred vision.
- Use of this medicine may cause prolonged and painful erection. If you or your child develops this effect, refer to the doctor immediately because of the potential for irreversible damage.
- The following heart problems have been reported with use of methylphenidate hydrochloride:
- Sudden death in patients suffering from heart problems or a heart defect, stroke and heart attacks in adults, increased blood pressure and heart rate.

Inform the doctor if you or your child suffers from any heart problem, heart defect, high blood pressure or if there is a family history of such problems. The doctor will check you or your child for heart problems before starting treatment with Phenidin. The doctor will regularly monitor your or your child's blood pressure and heart rate during the treatment with Phenidin.

Refer to a doctor immediately if you or your child develops symptoms of heart problems, such as chest pain, shortness of breath or fainting while using Phenidin.

- The following mental problems have been reported with use of methylphenidate hydrochloride:
- Onset or worsening of the following problems in all patients: behavioral or thought problems, bipolar disorder, aggressive or hostile behavior. In children and adolescents: occurrence of psychotic symptoms (e.g., hearing voices, believing in things that are not real or suspicious) or of manic symptoms.
- Inform the doctor of any mental problem you or your child has, of a family history of suicide, bipolar illness or depression.

- Refer to a doctor immediately if you or your child experiences onset or worsening of mental symptoms or problems during the treatment with Phenidin, especially seeing and hearing things that are not real, believing in things that are not real or suspicious.
- Circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon) have been reported with use of methylphenidate hydrochloride. The fingers or toes may feel numb, cold and painful. They can change their color from pale to blue, to red. Inform the doctor immediately if you experience numbness, pain, skin color change or sensitivity to temperature in the toes or fingers.
- Periodic blood tests should be performed in cases of prolonged use of the medicine.
- Long-term use of this preparation in children may cause slowed growth (in weight or height). The doctor can stop the treatment with the medicine in such case. The doctor may want to carefully monitor weight and height.
- If you are about to undergo surgery, inform the doctor that you are taking Phenidin. Do not take Phenidin on the day of the surgery if a certain type of anesthetic is used, as there is a chance of a sudden rise in blood pressure during the surgery.
- Phenidin can give a false-positive result in laboratory tests for amphetamines. This includes tests performed in branches of sport.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.

#### ■ Before starting treatment with Phenidin, tell the doctor if you have any of the following conditions:

- If you are pregnant, breastfeeding or plan to become pregnant, inform the doctor who will decide if you can take Phenidin.
- If you suffer from liver or kidney problems.
- If you have problems with swallowing or swallowing whole tablets.
- If you suffer from narrowing or blockage of the digestive system (in the esophagus, stomach or intestine).
- If you suffer from convulsions, epilepsy or abnormal brain wave test (EEG).
- If you are, or have ever been, addicted to alcohol or to any medicines or street drugs.
- If you, or anyone in your family, suffer from Tourette's Syndrome, recurrent, uncontrollable twitching in different parts of the body, or lack of control of any repetitive verbalizations.
- If you suffer, or have suffered in the past, from heart function problems (including a family history of heart diseases), from advanced vascular disease, from high blood pressure, from stroke or from heart attack.
- If you suffer from diseases related to a defect in the structure of the heart or if there is a family history of sudden death or death from heart diseases. Sudden death has been reported in association with use of preparations for treatment of ADHD in children suffering from a heart defect. Generally, Phenidin should not be used in children, adolescents or adults suffering from a heart defect.
- If you are being treated for depression or if you have symptoms of depression, such as feeling of sadness, feeling of lack of self-esteem and pessimism, or if there is a family history of depression or suicide.
- If you suffer from bipolar disorder: extreme mood swings. Mood fluctuates between mania exaggerated elation and depression.
- If you suffer from hallucinations (from abnormal thoughts, visions, or hearing of voices) or you have been diagnosed with psychosis, a type of mental illness.
- If you suffer from delusions (unrealistic thoughts and beliefs), feel extremely suspicious (paranoia), feel tense, anxious or agitated.
  If your behavior becomes aggressive or existing aggressive behavior
- If weight gain and/or growth in height in children and teenagers are slowed down. The doctor may want to carefully monitor weight and
- If you suffer from circulation problems in the fingers or toes.
- If you suffer from eye problems, such as cloudy vision, glaucoma, blurred vision, disturbed vision.

Tell the doctor if you suffer from any of the above listed conditions before starting treatment with Phenidin. This is because methylphenidate can make these conditions worse. The doctor will decide if you can use Phenidin.

- If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Do not take Phenidin if you are currently taking or if you have taken within 14 days before starting treatment with Phenidin, preparations for the treatment of depression from the MAOI group; taking MAOIs together with Phenidin may cause a sudden rise in blood pressure. It is especially important to inform the doctor or the pharmacist if you are taking any of the following:
- Medicines for the treatment of depression, such as tricyclic antidepressants and serotonin reuptake inhibitors (such as fluoxetine, imipramine, amitriptyline, paroxetine, fluvoxamine, citalopram and others).
- Antiepileptics (such as: phenobarbital, phenytoin, primidone).
- Medicines for lowering or raising blood pressure.
- Alpha-2 receptor agonists, such as clonidine
- Medicines that affect the dopaminergic system (for treatment of Parkinson's disease or psychosis).
- Certain cough or cold remedies that contain ingredients that can affect blood pressure.
- Anticoagulants (such as warfarin and others).
- Use of the medicine and food: Swallow the tablet with water or another liquid. The tablet can be taken with or without food.
- Use of the medicine and alcohol consumption: Do not drink alcohol while using the medicine. Alcohol can worsen the side effects of the medicine. Remember that there are food and medicines that contain alcohol.
- Pregnancy and breastfeeding: If you are pregnant, breastfeeding or are planning to become pregnant, report to the doctor, who will decide if you can take Phenidin.
- Driving and use of machines: Stimulating agents may impair your capacity to operate dangerous machines or to drive a vehicle. Act

with caution, and only perform these activities if you are sure that the medicine does not affect your capacity to drive or to operate dangerous

■ Important information regarding some of the ingredients of the medicine: Phenidin contains a source of sucrose. Consult the doctor before starting to use the medicine if you suffer from intolerance to certain sugars.

# 3. HOW SHOULD THE MEDICINE BE USED?

Always use according to the doctor's instructions. Check with the doctor or pharmacist, if you are not certain how to use it.

The dosage and treatment regimen will be determined by the doctor only.

Take the tablet once a day, in the morning. Wait one day before taking an additional dose.

Swallow the tablet with water or another liquid.

Phenidin is a prolonged-release tablet. It releases the medicine to 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.

The tablet can be taken with or without food.

## Do not exceed the recommended dose

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

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

Adhere to the treatment as recommended by the doctor.

The doctor may occasionally stop treatment with Phenidin for a while in order to check signs of ADHD.

The doctor may send you for periodic blood tests, will regularly monitor heart rate and blood pressure during the treatment with Phenidin.

The height and weight of children taking Phenidin should be regularly

monitored. Treatment with Phenidin may be terminated if a problem is observed during this monitoring.

If you stop taking the medicine, the symptoms of ADHD may recur, or undesirable side effects, such as depression, may appear. The

or undesirable side effects, such as depression, may appear. The doctor may want to gradually lower the dosage of the medicine before completely stopping use of the medicine. Consult with the doctor before stopping use of the medicine.

Do not take medicines in the dark! Check the label and the dose <u>each</u>

time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist

#### 4. SIDE EFFECTS:

As with any medicine, use of Phenidin tablets may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop the treatment and refer immediately to the doctor if you feel any of the following:

High body tomporature, muscle etiffness, decreased electrons loss of

 High body temperature, muscle stiffness, decreased alertness, loss of consciousness (rare).

# Refer to the doctor immediately if you feel 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.
- Paralysis, or problems with movement and vision, difficulties with speech (these can be signs of cerebrovascular problems), inflammation or blockage of arteries in the brain.
- Chest pains or a rise in heart rate or palpitations, shortness of breath, fainting, heart attack, sudden death.
- Uncontrollable movements, spasms, convulsions.
- Unusual thoughts or dreams, confusion, lack of interest, change in sleep patterns, unclear speech, thinking about or wanting to commit suicide, suicide attempts, unusual excitedness, overactivity and disinhibition (mania).
- Blockage of the esophagus, stomach, small or large intestine, in patients already suffering from narrowing of these organs.
- Rise in blood pressure, anxiety, nervousness, depression, extreme mood swings, hostility, rash, fever, repeated accidental injuries, hallucinations, excessive muscle movements, nosebleed, hair loss, itching, increased need to pass urine, blood in the urine, slowed growth rate, mental disturbances, skin disorders, double vision, blurred vision, difficulties focusing vision.
- With prolonged use in children, Phenidin may cause slowed growth rate (height and weight). The doctor will monitor the weight and height of the child. If they are slowed down, treatment with Phenidin may be stopped for a while.

#### Additional side effects: Very common side effects:

Abdominal pain, decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, weight loss, nervousness, increased sweating.

# Common side effects:

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

# Additional side effects that have been reported in clinical trials: Low white blood cell count (leukopenia), dry eyes, impaired accommodation (visual focus), hot flushes, abdominal discomfort.

diarrhea, weakness, fatigue, exhaustion, feeling tense and nervous,

feeling thirsty, sinusitis, increased levels of the alanine aminotransferase enzyme, increased blood pressure, heart murmur, increased heart rate, muscles spasms, lethargy, sleepiness, psychomotor hyperactivity, anger, excessive alertness, excessive awareness of surroundings, mood swings, frequent fluctuations in mood, anxiety attack, trouble sleeping, tendency to cry, uncontrollable speech and body movements (Tourrettetics), erection problems, shortness of breath, skin rash, macular rash, hypertension.

### Additional side effects reported upon use:

Pancytopenia (simultaneous reduction in red blood cell, white blood cell and platelet counts), decreased platelet count (thrombocytopenia) thrombocytopenic purpura (bleeding characteristic of very low platelet count), angina pectoris, reduced heart rate, premature beat, heart rhythm abnormalities (supraventricular tachycardia), double vision dilated pupils, vision problems, chest pains, chest discomfort, decreased effect of the medicine, high fever, reduced response to the medicine, 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, lumps and/or skin infection. rash, increased blood levels of the alkaline phosphatase, increased bilirubin levels in the blood, increased liver enzyme levels in the blood, abnormal white blood cell and platelet counts, joint pains, muscle pains, muscle spasms, rhabdomyolysis, epileptic attack, dyskinesia (repeated involuntary movements), disorientation, hallucinations (visual or auditory), mania, libido problems, 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, typically following exposure to cold (Raynaud's syndrome), prolonged and painful erection.

#### Side effects as a result of overdose:

Nausea, anxiety, tremor, increased uncontrollable movements, muscle spasm, convulsions (followed by coma), ecstatic feeling, feeling of confusion, hallucinations (seeing, feeling and hearing things that are not real), sweating, flushing, headache, high fever, changes in heart rate, high blood pressure, dilation of pupils, dryness in nose and mouth.

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

Side effects can be reported to the Ministry of Health by clicking on the

link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (<a href="www.health.gov.il">www.health.gov.il</a>) that directs you to the online form for reporting side effects or you can also use this link: <a href="https://forms.gov.il/globaldata/getsequence/getsequence">https://forms.gov.il/globaldata/getsequence/getsequence</a>.

<u>aspx?formType=AdversEffectMedic@moh.gov.il</u>
You can also report side effects by email to: <u>safety@trima.co.il</u>

#### 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from a doctor.
- Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Close the bottle tightly.
- Keep out of reach and sight of children.6. FURTHER INFORMATION:

In addition to the active ingredient, the 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 Casting

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

Each Phenidin 18 mg tablet contains 10.9 mg sucrose.

Each Phenidin 27 mg tablet contains 16.9 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 the contents of the package: Phenidin 18 mg: a round yellowish to yellow tablet. Each package contains 30 tablets.

Phenidin 27 mg: an oblong yellow tablet, with break scores on both sides. Each package contains 30 tablets.

Phenidin 36 mg: an oblong white to off-white tablet with break scores on both sides. Each package contains 30 tablets.

Phenidin 54 mg: an oblong reddish to red tablet with break scores on

both sides. Each package contains 30 tablets.

Registration holder name and address: Trima Trading (1961) Ltd.

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

This leaflet was checked and approved by the Ministry of Health in November 2018.

Registration numbers of the medicine in the National Drug Registry of

the Ministry of Health: 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

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