Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Tarophen 18 mg
Tarophen 27 mg
Tarophen 36 mg
Tarophen 54 mg
Extended-release tablets

Active ingredient

Each Tarophen 18 mg tablet contains 18 mg methylphenidate hydrochloride.
Each Tarophen 27 mg tablet contains 27 mg methylphenidate hydrochloride.
Each Tarophen 36 mg tablet contains 36 mg methylphenidate hydrochloride.
Each Tarophen 54 mg tablet contains 54 mg methylphenidate hydrochloride.

Inactive ingredients and allergens in this medicine: see 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?

Tarophen 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.

Therapeutic group: central nervous system stimulant.
Tarophen can improve attention and concentration, and reduce impulsiveness and hyperactivity in individuals with ADHD. Tarophen should be given as part of an ADHD treatment program that may include counseling or other therapies.

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').
- is very anxious, mentally tense, or agitated (suffers from restlessness)
- has an eye problem called glaucoma (increased intraocular pressure)
- has tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are involuntary repeated movements or sounds.

- is taking or has taken an antidepressant from the monoamine oxidase inhibitor (MAOI) group within the last 14 days before starting Tarophen treatment.

Special warnings about using this medicine
Before beginning treatment with Tarophen, tell your doctor if you or your child has any of the following conditions or a family history of any of the following conditions:
- heart function problems, heart defects, or high blood pressure
- a family history of sudden death
- mental problems such as psychosis, mania, bipolar disorder, or depression
- a family history of suicidal ideation
- tics or Tourette's syndrome
- seizures or abnormal brain scan (EEG) results
- circulation (blood flow) problems in fingers and toes
- digestive system problems – esophagus, stomach, or intestine (small or large)
- addiction/dependence or abuse of alcohol, prescription medicines, or recreational drugs

The following problems were reported with use of methylphenidate hydrochloride and other stimulants:
Heart-related problems
- sudden death in patients with heart problems or a heart defect
- stroke and heart attacks in adults
- increased blood pressure and pulse

In general, Tarophen should not be used in children, adolescents, or adults who have a heart defect or other serious heart problems.
Contact a doctor immediately if you or your child develops symptoms of heart problems, such as chest pain, shortness of breath, or fainting while using Tarophen.

Mental (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 (like hearing voices, believing in things that are not real, or feeling suspicious) or of manic symptoms.
Contact your doctor immediately if you or your child experiences new onset or worsening of mental symptoms or problems while using Tarophen, especially seeing and hearing things that are not real, believing in things that are not real, or feeling suspicious.

Prolonged and painful erections (priapism)
Onset of prolonged and painful erections has been reported with use of methylphenidate. If you or your child develops this effect, contact your doctor immediately, because there is a risk of irreversible damage.

Circulation (blood flow) problems in the toes and fingers (peripheral vasculopathy, including Raynaud's phenomenon)
- The fingers or toes may feel cold and painful or numb.
- The fingers or toes may change color from pale to blue, to red.

Inform your doctor if you notice numbness, pain, skin color change or sensitivity to temperature in the toes or fingers.
Contact your doctor immediately if you or your child gets bruises on the toes or fingers while taking Tarophen.

Dependence and addiction
Using this medicine can lead to dependence or abuse. Store the medicine in a safe place to prevent abuse. Selling this medicine or passing it on to other people may harm them and is illegal.

Children and adolescents
Do not use Tarophen in children under the age of 6, as it has not been studied in this age group.

Tests and follow-up
Before starting treatment with Tarophen, 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 the course of treatment with Tarophen.
The height and weight of children taking Tarophen should be monitored frequently.
Tarophen 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 nonprescription medicines and dietary supplements, tell your doctor or pharmacist.
Tarophen in combination with certain medicines may cause severe side effects. It is sometimes necessary to adjust the dosages of these medicines while taking Tarophen. Your doctor will decide whether Tarophen can be taken with other medicines.
In particular, tell your doctor or pharmacist if you or your child is taking any of the following:
- monoamine oxidase inhibitors (MAOIs). Do not take Tarophen if you or your child is currently taking or has taken MAOI antidepressants within the last 14 days before starting treatment with Tarophen (also see section 2 under ‘Do not use this medicine’).
- medicines used to treat depression, such as tricyclic antidepressants and serotonin reuptake inhibitors
- anti-epileptics (such as phenobarbital, phenytoin, primidone)

- anticoagulants (such as warfarin)
- medicines used to treat blood pressure
- vasoconstrictors
- medicines used to treat colds or allergies that contain anticongestants.

Know the medicines that you or your child takes. Show the doctor and pharmacist the list of medicines that you or your child is taking. Do not start taking new medicines during the course of treatment with Tarophen without first talking to your doctor.

Using this medicine and food
Swallow the tablet whole with water or another liquid. The tablet can be taken with or without food.

Pregnancy, breastfeeding, and fertility
If you are pregnant, breastfeeding, or planning to become pregnant, inform the doctor, who will decide if you can take Tarophen.

Driving and using machines
Stimulants may impair the ability to operate dangerous machines or drive a vehicle. 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
Sodium – This medicine contains less than 1 millimole (23 mg) sodium per tablet, i.e., it is essentially considered "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.
Tarophen is an extended-release tablet. It releases the medicine into the body throughout the day. Therefore, do not chew, crush, or halve the tablet.
Swallow the tablet whole with water or another liquid.
Tell your doctor if you or your child cannot swallow the tablet whole. It may be necessary to prescribe you or your child a different medicine.
The tablet can be taken with or without food.
Take a tablet once a day, in the morning.
Tarophen tablets do not completely dissolve in the body. After all the medicine has been released, you may sometimes notice an empty tablet in the stool. This is normal.
Your doctor may stop your Tarophen treatment for a while from time to time in order to check the symptoms of ADHD.

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

vomiting, restlessness, increased involuntary movements, muscle spasms, seizures, feeling of confusion, hallucinations (seeing, feeling or hearing things that are not real), increased sweating, headache, high fever, heart rate changes and disturbances, hypertension, 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 the doctor. Adhere to the treatment as recommended by your doctor.

If you stop taking the medicine, consult your doctor before stopping your medicine.

Do not take medicines in the dark! Check the label and dose <u>every time</u> 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 Tarophen tablets 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:

- 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 difficulty in 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 or other stimulants: increased blood pressure and pulse, stroke and heart attack in adults, sudden death in patients suffering from heart problems or a heart defect.
- mental (psychiatric) problems – new onset or worsening of mental symptoms or mental problems during the course of treatment with Tarophen, especially, seeing and hearing things that are not real, believing things that are not real or feeling suspicious; behavioral or thought problems, depression, bipolar disorder, restlessness (excessive muscle movement), aggressive or hostile behavior
- mental (psychiatric) problems in children and adolescents: onset of psychotic symptoms (like hearing voices, believing in things that are not real, or feeling suspicious) or of manic symptoms
- prolonged and painful erections (priapism). An immediate examination by your doctor is necessary because of the risk of irreversible damage.
- numbness, pain, change in skin color or sensitivity to temperature, or appearance of unexplained sores on the toes or fingers. These could be circulation problems in the fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).

- Tarophen may cause slowed growth rate (height and weight) in children.
- seizures, especially 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 – affect more than one in ten users
- decreased appetite
- dry mouth
- insomnia
- dizziness
- abdominal pain
- increased sweating
- headache
- nausea
- anxiety
- weight loss
- nervousness

Common side effects – affect 1–10 in 100 users
vomiting, fever, nasopharyngitis (inflammation of the mucosa of the nose and pharynx, with suppurating nasal discharge), cough, pharyngeal pain, rapid pulse, palpitations, vertigo (spinning sensation), blurred vision, indigestion, constipation, upper respiratory tract infection, reduced appetite, anorexia (eating disorder), muscle tightness, tremor, prickling (paresthesia), sedation, tension headache, depressed mood and depression, restlessness, aggression, decreased libido, feeling confused, teeth grinding, tension, emotional instability.

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

Additional side effects reported with use of this medicine (post-marketing)
pancytopenia (too low numbers of all blood cells – red, white and platelets), decreased platelet count (thrombocytopenia), thrombocytopenic purpura (bleeding characteristic of a very low platelet count);
angina pectoris, slow pulse, heart rhythm disturbances, double vision, dilated pupils, vision problems, chest pain, chest discomfort, reduced effect of the medicine or reduced 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, skin peeling, hives (a skin disease), itching, skin irritation and/or skin infection, rash;
increased blood level of the enzyme alkaline phosphatase, increased bilirubin level in the blood, increased level of liver enzymes in the blood, abnormal white blood cell and platelet counts;
joint pain, muscle pain, muscle spasms, rhabdomyolysis;
seizure, dyskinesia (repeated involuntary movements), serotonin syndrome (when combined with certain medicines), feeling disoriented, 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 following 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) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.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.
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.
Storage conditions: Store below 25°C. Close the bottle tightly.

6. Additional information
In addition to the active ingredient, this medicine also contains:

polyethylene oxide, cellulose acetate, sodium chloride, Opadry 03K19229 clear, poloxamer, povidone, succinic acid, stearic acid, colloidal silicon dioxide, pigment blend PB-2179 green (black iron oxide and yellow iron oxide), phosphoric acid, lake blend LB-2262 pink (allura red AC, indigo carmine), Opacode black S-1-17823.
The 18 mg extended-release tablets also contain Opadry 03K520061 yellow.
The 27 mg extended-release tablets also contain Opadry 03K57528 grey.
The 36 mg extended-release tablets also contain Opadry 03K18533 white.
The 54 mg extended-release tablets also contain Opadry 03K15646 red.

What the medicine looks like and contents of the pack:
Tarophen 18 mg: a cylindrical yellow film-coated tablet, imprinted with “18”.
Tarophen 27 mg: a cylindrical grey film-coated tablet, imprinted with “27”.
Tarophen 36 mg: a cylindrical white film-coated tablet, imprinted with “36”.

Tarophen 54 mg: a cylindrical brown-red film-coated tablet, imprinted with "54".
Packs contain 30 or 100 tablets.
Not all pack sizes may be marketed.

Registration holder's name and address: Taro International Ltd., 14 HaKitor St., Haifa Bay 2624761.

Manufacturer's name and address:
Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540 USA

Revised in July 2023 according to MOH guidelines.

Registration numbers of the medicine in the Ministry of Health's National Drug Registry:
Tarophen 18 mg – 172-99-36850-99
Tarophen 27 mg – 173-01-36851-99
Tarophen 36 mg – 173-02-36852-99
Tarophen 54 mg – 173-03-36853-99