PATIENT PACKAGE LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only.

Cabotrim 1, Cabotrim 2

Tablets

Active ingredient:
Cabotrim 1: Each tablet contains Cabergoline 1 mg
Cabotrim 2: Each tablet contains Cabergoline 2 mg

Inactive ingredients in the preparations - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the 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 treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.
The medicine is not intended for youngsters under the age of 16.

- Prevent pregnancy for at least one month after completing use of the medicine. Before using the medicine, and if your period is more than three days late, tests to rule out pregnancy should be performed. While using the medicine, nonhormonal contraceptive methods should be used. In case of pregnancy, stop taking the medicine immediately.
- It is recommended to monitor blood pressure, especially in the first days of treatment, since especially in the first days of treatment, low blood pressure may develop.
- The preparation belongs to a group of medicines which might cause the following effects: addictive gambling, overspending, compulsive eating, increased sexual desire (libido) and hypersexuality. These effects generally subside upon reduction of the dosage or treatment modification by the doctor.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For treatment of Parkinson's disease symptoms.

Therapeutic group: dopamine receptor agonist.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:
- you are sensitive/allergic to the active ingredient or to any of the other ingredients contained in the medicine and/or to ergot alkaloids.
- you are suffering from uncontrolled hypertension.
- you are suffering, or have suffered in the past, from pericardial or pulmonary and/or retroperitoneal fibrotic reactions (thickening and scarring).
- you are suffering from damage to the cardiac valves.
- you are pregnant or breastfeeding.

Before treatment with Cabotrim, tell the doctor if:
- you are suffering, or have suffered in the past, from impaired function of: the lungs/respiratory system (such as: asthma), the heart and/or blood vessels, the liver, the kidney/urinary system, the digestive system (e.g., ulcer), Raynaud's syndrome (which causes a cold sensation in the hands and legs), a history of psychotic disorders.
- you are suffering from low blood pressure and/or are being treated with antihypertensives.
- you took pergolide in the past.

Special warnings regarding use of the medicine:
- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Before using the medicine, tests to rule out pregnancy should be performed. While using the medicine, nonhormonal contraceptive methods should be used. In case of pregnancy, stop taking the medicine immediately. Prevent pregnancy for at least one month after completing use of the medicine.
- Especially in the first days of treatment low blood pressure may develop.
- The preparation belongs to a group of medicines which might cause the following effects: addictive gambling, overspending, compulsive eating, increased libido and hypersexuality. These effects generally subside upon reduction of the dosage or treatment modification by the doctor.
- In certain cases, long-term treatment with cabergoline may cause fibrosis and inflammatory conditions of the lungs, pericardium and the retroperitoneum as well as cardiac valve damage. In some cases, cardiac valve damage improves upon cessation of treatment with cabergoline. Patients who are taking cabergoline and experience breathing disturbances or difficulties, are advised to refer to the doctor who will consider performing a chest x-ray, blood sedimentation and/or serum creatinine measurement.
- During treatment with the preparation, refer to a doctor immediately if you experience the following signs: difficulty breathing, shortness of breath, prolonged cough and/or chest pains, pains and swelling in the waist area and/or heart failure.

❗ Tests that should be performed before using the medicine:
- Before using the medicine, tests to rule out pregnancy should be performed.
- The patient must undergo cardiovascular evaluation including an echocardiogram. It is also recommended to perform, before starting the treatment, blood sedimentation test, lung function/chest x-ray and kidney function tests. Do not use the preparation if damage to the cardiac valves is diagnosed.

❗ If you are taking, or have recently taken, other medicines including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:
- antiemetics (e.g., metoclopramide) - might impair the effectiveness of Cabotrim.
- macrolide antibiotics (e.g., erythromycin) - may cause side effects.
- medicines to treat migraine (e.g., ergot-alkaloids) - may cause side effects.
- medicines to treat mental disorders (e.g., phenothiazines, thioxanthenes, butyrophenones) - might impair the effectiveness of Cabotrim.
- antihypertensives - may cause side effects.

❗ Use of the medicine and food:
Swallow the medicine after a meal.

❗ Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, do not use the preparation.
Before using the medicine, tests to rule out pregnancy should be performed. While using the medicine, nonhormonal contraceptive methods should be used. In case of pregnancy, stop taking the medicine immediately. Prevent pregnancy for at least one month after completing use of the medicine.
Do not breastfeed when using the medicine, since the medicine may affect the production of milk and its quantity.

❗ Driving and use of machinery:
Use of this medicine may impair alertness and may cause sudden onset of sleep. If you experience these effects, do not drive, operate dangerous machinery or perform any activity that requires alertness or coordination until the effects subside.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the manner of use.
The dosage and treatment regimen will be determined by the doctor only.
The recommended initial dosage is generally 1 mg, once a day. The doctor may increase the dosage as needed. The recommended maintenance dosage is 2-3 mg per day, in one dose. Do not take a dosage greater than 3 mg per day.
Do not exceed the recommended dose.
Do not chew! Swallow the medicine with a little water after a meal, to reduce the occurrence of side effects.
The tablet can be crushed.

Tests and Follow-up:
- The first echocardiogram is must be performed after 3-6 months of treatment and should be repeated every 6-12 months. If damage or worsening of the condition of the cardiac valves is observed, stop treatment with the preparation.
- It is recommended to perform periodic monitoring that includes blood, heart, lung, and kidney tests.

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

If you forgot to take the medicine, take it when you remember and continue treatment as usual. Do not take a double dose.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of cabergoline may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop treatment and refer to the doctor immediately if the following effects develop:
- Very common side effects (occur in more than one in ten users) that may indicate fibrosis (thickening and scarring) of the cardiac, pulmonary and/or retroperitoneal tissue such as: faint feeling, chest/rib/waist/back/pelvic pain, movement disorders, swelling of the legs, shortness of breath, breathing difficulties, heart rhythm changes/palpitations.
- An allergic reaction manifested by skin rash, itching, skin blisters, swelling of the face, tongue, neck and/or limbs, shortness of breath, worsening of asthma, shock.

Refer to the doctor as soon as possible if the following effects develop:
- Common effects: psychotic disorder (e.g., urge to gamble, increased libido, hypersexuality, overspending, compulsive eating), uncontrollable or involuntary movement of the limbs, confusion, hallucinations, sudden onset of sleep, weakness, changes in blood test results and/or liver functions (increased enzymatic activity), chest pain.
- Uncommon effects: delusions, edemas, low blood pressure.
- Effects of unknown frequency: vision disturbances, hair loss, aggressiveness, leg cramps, acne, depression.

Additional side effects:
- Very common (occur in more than one in ten users): nausea, gastritis.
- Common (occur at a frequency of up to one in ten users): vomiting, indigestion (dyspepsia), abdominal pain, constipation, sleep disturbances, headache, dizziness, sleepiness, vertigo, tingling.
- Uncommon (occur at a frequency of up to one in one hundred users): sensation of pain (burning) and redness in the skin of the hands and legs, when standing - sudden drop in blood pressure, fatigue, nosebleed.
- Frequency unknown: feeling hot, flushing, sensation changes, tingling, muscle weakness.

If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/label. The expiry date refers to the last day of that month.
- Store in a cool, dark and dry place, below 25°C.
- After first opening, the preparations can be used for up to 90 days.

6. FURTHER INFORMATION

- In addition to the active ingredient, the preparations also contain the following inactive ingredients:
  Microcrystalline cellulose, Croscarmellose sodium, Citric acid (Anhydrous), Magnesium stearate.
- **What the medicine looks like and the contents of the package -**
- Each package contains 30 white to off-white tablets with a breakline on one side.
- Manufacturer and license holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel.
- This leaflet was checked and approved by the Ministry of Health in January 2015.
- Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
  Cabotrim 1: 143.87.31546.01
  Cabotrim 2: 141.30.32035.00

Maabarot 4023000
Israel Pharmaceutical Products
Maabarot Ltd.