

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

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

## PARTANE 5 mg, Tablets

The active ingredient and its quantity:

Each tablet contains:

Trihexyphenidyl Hydrochloride 5 mg

For a list of the inactive ingredients, please see section 6.

**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 the 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.

This medicine is not intended for patients under 21 years of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

- As a treatment that helps in all forms of Parkinson's disease.
- To regulate extrapyramidal disorders caused by medicines that affect the central nervous system, such as phenothiazines.

**Therapeutic group:** Anticholinergic, antiparkinsonism.

### 2. BEFORE USING THE MEDICINE:

**☒ Do not use the medicine if:**

- you are sensitive (allergic) to the active ingredient (trihexyphenidyl) or to any of the other ingredients of this medicine (for the list of inactive ingredients, see section 6 "Further information").

**Special warnings regarding use of the medicine:**

**• Before the treatment with Partane, tell the doctor if:**

- you are suffering from glaucoma.
- you are suffering, or have suffered in the past, from heart, liver or kidney disease or if you are suffering, or have suffered in the past, from high blood pressure.
- you are suffering, or have suffered in the past, from prostate problems.
- you have trouble passing urine.
- you are suffering from a stomach ulcer or from severe heartburn or from any other digestive system disorder.
- you are suffering from myasthenia gravis (severe muscle weakness).
- you are suffering from tardive dyskinesia (manifested by abnormal movements of the face and tongue).
- you are elderly or under 21 years of age.
- you are sensitive to any food or medicine.
- you are pregnant, planning to become pregnant or are breastfeeding.
- Use with caution in hot weather, and particularly when exercising or when in a sauna or a whirlpool (this medicine reduces sweating and can thereby lead to overheating of the body).
- Use of this medicine may impair vision. Before and during the treatment with this medicine, perform an eye examination.
- Use in the elderly requires special supervision regarding dosage and special side effects, particularly in the elderly suffering from arteriosclerosis.

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** In particular, if you are taking:

- Levodopa to treat Parkinson's disease.
- Monoamine oxidase inhibitors (e.g., moclobemide, tranlycypromine) or tricyclic antidepressants (e.g., amitriptyline) to treat depression.
- Phenothiazines (e.g., chlorpromazine, thioridazine) or clozapine to treat mental illness.
- Disopyramide for treatment of irregular heart rate.
- Antihistamines for treatment of allergies.
- Amantadine for treatment of viral infections.
- Nefopam, a painkiller.
- Metoclopramide or domperidone (for treatment of nausea and vomiting).
- Parasympathomimetics (e.g., neostigmine, bethanechol) for treatment of urinary retention.

**If Use of the medicine and food:**

Swallow the medicine with a meal (immediately before or immediately after a meal).

If the medicine causes severe dryness in the mouth, take the medicine before the meal, unless it causes nausea. If you took the medicine after a meal, the thirst can be relieved by sucking hard sugarless candies, chewing gum or drinking water.

**If Use of the medicine and alcohol consumption:**

**Do not drink wines** or alcohol beverages during the course of treatment with the medicine.

**If Pregnancy and breastfeeding:**

If you are pregnant, plan to become pregnant or are breastfeeding, do not use the medicine without consulting the doctor before starting treatment.

**If Driving and using machines:**

Use of this medicine may cause blurred vision and dizziness.

Do not drive or operate machines if you are suffering from these effects.

**If Important information about some of the ingredients in the medicine:**

The preparation contains lactose. If you have been told by a doctor that you have an intolerance to certain sugars, refer to a doctor before taking the medicine.

### 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.
- The dosage varies from patient to patient, depending on the symptoms. The doctor will usually start with a low dosage and will increase the dosage gradually.

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

This medicine is not intended for patients under 21 years of age.

The doctor may recommend to reduce the dosage if you are 65 years of age or older.

Use this medicine at set intervals, as determined by the attending doctor.

**Do not exceed the recommended dose.**

Do not chew! If necessary, the tablets can be crushed or halved to ease swallowing.

Swallow the medicine with water. Take the medicine with a meal.

### Tests and follow-up –

When using this medicine, the patient should be monitored by the doctor.

Before starting treatment and during the treatment with this medicine perform an eye examination.

**If you accidentally took a higher dosage,** 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. Signs of overdose can include: depression, difficulty breathing, dilated or slowly reacting pupils, rapid breathing, rapid pulse, high blood pressure, hot and dry skin, flushing.

**If you forgot to take this medicine** at the required time, take a dose as soon as you remember; but if you have to take the next dose within two hours – skip the forgotten dose and continue taking the tablets as per the regular dosing schedule and consult a doctor or pharmacist. Never take two doses together to compensate for the forgotten dose.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a doctor.

### If you stop taking the medicine

Do not stop taking the medicine suddenly. Sudden discontinuation may cause severe side effects. If the dosage has to be lowered, the doctor will lower the dosage gradually.

- Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
- If you have further questions regarding use of this medicine, consult a doctor or pharmacist.

### 4. SIDE EFFECTS:

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

**Immediately refer to a doctor or proceed to an emergency room if you are suffering from any of the following side effects (very rare):**

- Allergic reaction such as swelling of the eyelids, face or lips, mouth or tongue or skin rash, itching.
- Difficulty breathing or tightness in the chest.
- Difficulty swallowing.

**Refer to a doctor as soon as possible if you are suffering from any of the following side effects (rare):**

- Restlessness or agitation.
- Confusion or delusions (loss of the sense of reality).
- Hallucinations.
- Insomnia.
- False sense of well-being.
- Immediate-term or short-term memory loss.
- Worsening of myasthenia gravis (exhaustion or severe muscle weakness).
- Dilated pupils and lack of near vision.
- Eye discomfort and increased sensitivity to light.
- Painful increased pressure in the eye.
- Rapid heart rate.
- Vomiting.
- Redness and dryness of the skin or skin rash.
- Inability to pass urine or difficulty passing urine.
- Thirst.
- Fever (raised body temperature).

### Additional side effects (common):

Dryness of the mouth.

Constipation.

Blurred vision or dizziness.

Nausea or nervousness.

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

**Side effects can be reported to the Ministry of Health via the online form at the following link:**

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il>

### 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 and sight 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) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C.
- Do not throw medicines into the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

### 6. FURTHER INFORMATION:

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

Lactose monohydrate, corn starch, microcrystalline cellulose, alginic acid, keltose, magnesium stearate.

Each tablet contains 250 mg lactose monohydrate.

**What the medicine looks like and the contents of the package:**

A white, biconvex tablet.

Each package contains 50, 100 or 1,000 tablets.

Not all package sizes may be marketed.

**Manufacturer and license holder:** Taro Pharmaceutical Industries Ltd., Haifa Bay, 2624761.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 021 57 21465 00

This leaflet was checked and approved by the Ministry of Health in July 2015.