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

This medicine is dispensed with a doctor's prescription only

Profex 150 mg Film-coated tablets	**Profex 300 mg Film-coated tablets**
Active ingredient and quantity: Each tablet contains: propafenone hydrochloride 150 mg	Active ingredient and quantity: Each tablet contains: propafenone hydrochloride 300 mg

Inactive ingredients and allergens: 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 to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is not indicated for use in children.

1. What is this medicine intended for?

To prevent and regulate arrhythmias.

Therapeutic group: anti arrhythmic medicine.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (propafenone hydrochloride) or to any of the other ingredients in this medicine (see section 6).
- You have a heart condition called Brugada syndrome, which causes you to have a potentially life-threatening heart rhythm.
- You had a heart attack in the previous three months.
- You suffer from heart failure or any heart problems (in addition to your irregular heart rhythm).
- You have a slow heart rate or low blood pressure.
- You suffer from breathing problems, such as chronic bronchitis or emphysema.
- You have a disturbance in the salts, such as sodium or potassium, in your blood.
- You have severe muscle weakness (myasthenia gravis).
- You are taking ritonavir (an antiviral medicine for AIDS).

Special warnings about using this medicine
Before using Profex, tell your doctor if:

- You are pregnant or planning to become pregnant.

- You are breastfeeding.
- You suffer from breathing problems, such as asthma.

Additional warnings:
- Tell your surgeon or dentist that you are taking Profex if surgery is planned. It may affect the anaesthetic used.
- If you have a pacemaker, the pacing mode may need to be reprogrammed.

Children and adolescents
This medicine is not indicated for use in children.

Tests and follow-up
Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment with the medicine to monitor your individual dose.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Medicines that affect the activity of the heart such as amiodarone, digoxin, quinidine
- Medicines to prevent blood clots (e.g., warfarin)
- Antibiotics (e.g., erythromycin or rifampicin)
- Any of the group of medicines known as beta-blockers (used to treat high blood pressure)
- Antiviral medicines (e.g., ritonavir)
- Any antipsychotics or tricyclic antidepressants or medicines in a related group (e.g., amitriptyline, dothiepin, desipramine)
- Any other antidepressants, such as venlafaxine, fluoxetine, paroxetine
- Cimetidine (for treatment of a peptic ulcer)
- Ciclosporin (for suppression of the immune system and prevention of transplant rejection or in the treatment of arthritis or psoriasis)
- Theophylline (used in the treatment of asthma)
- Ketoconazole (an antifungal)
- Phenobarbital (for epilepsy)

Using this medicine and food
Do not take with grapefruit juice.
Take the medicine after a meal with some water.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before using this medicine.

Driving and using machines
It is not advisable to drive, operate machinery or do anything that requires you to be alert until you know how the medicine affects you. This is because the medicine can cause blurred vision, dizziness, tiredness and low blood pressure in some people.

Important information about some of this medicine's ingredients

The preparation contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.
Use this medicine at the scheduled times, as determined by the doctor.
The dose may need to be adjusted for the elderly, patients with liver or kidney diseases and patients with a low body weight.

Do not exceed the recommended dose.

Administration
Swallow the tablet after a meal, with some water.
There is no information about crushing/splitting/chewing.

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, take the dose as soon as you remember. If it is almost time for the next dose, skip the forgotten dose; under no circumstances should you take two doses together on the same day.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine without your doctor's advice, your condition may get worse. It is important to keep taking the medicine until your doctor tells you to stop. Even if your health improves, do not stop taking this medicine without consulting your doctor.

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 Profex may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Tell your doctor immediately if you develop:

- Seizures.
- Life-threatening irregular heartbeat.
- Heart problems which can cause shortness of breath or ankle swelling.
- A rash, itching or skin reddening or other signs of an allergic reaction such as difficulty breathing. Although these are rare, they can be serious.

- Yellowing of the skin and/or the whites of the eyes, as these may be a sign of liver problems (blockage of flow from the liver (cholestasis), inflammation of the liver (hepatitis)) or blood problems.
- You start to bruise easily or if you develop a very sore throat with a high fever, as in very rare cases, treatment may affect the amount of white blood cells and platelets in the blood.

Additional side effects

Very common side effects (affect more than 1 in 10 patients):
Dizziness, heart palpitations, heart rhythm disorders.

Common side effects (affect less than 1 in 10 patients):
Anxiety, difficulty sleeping, headache, alteration of taste or a bitter taste, blurred vision, abnormal heart rhythm, shortness of breath, stomach pain, feeling or being sick, diarrhoea, constipation, dry mouth, liver disorders, chest pain, feeling weak or tired, fever.

Uncommon side effects (affect less than 1 in 100 patients):
Loss of appetite, nightmares, fainting, ataxia (problems with or loss of coordination), low blood pressure, vertigo (spinning sensation), a tingling or pricking sensation of the skin, numbness, bloating, flatulence, redness of skin and itchy skin, impotence, irregular (slow or fast) heartbeat.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
Severe reduction in the number of white blood cells which makes infections more likely, confusion, tremor, rigidity, muscle stiffness, restlessness, a fall in the blood pressure on standing up from lying down, which may cause dizziness, lightheadedness or fainting, retching, stomach problems, lupus-like syndrome (an allergic condition which causes joint pain, skin rashes and fever), a reversible drop in sperm count has occasionally been reported with high doses of the drug, pus-filled skin outbreaks.

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 immediately.

Reporting side effects
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 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.
- **Storage conditions:** Store below 25°C.

- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

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

Microcrystalline cellulose, pregelatinized starch, povidone, colloidal silicon dioxide, magnesium stearate, lactose monohydrate, HPMC 2910, titanium dioxide, macrogol.

What the medicine looks like and contents of the pack:

Profex 150 mg, Profex 300 mg - round white film-coated biconvex tablet, smooth on both sides.
Each pack contains 30 tablets in blister pack.

Manufacturer and registration holder:

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761

Registration number of the medicine in the Ministry of Health's National Drug Registry:

Profex 150 mg: 133 93 29804 00
Profex 300 mg: 133 92 29805 00

This leaflet was revised in July 2021 according to MOH guidelines.