

## **Package leaflet: Information for the user**

### **Propafenone Hydrochloride 150mg Film-coated Tablets Propafenone Hydrochloride 300mg Film-coated Tablets Propafenone Hydrochloride**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Propafenone Hydrochloride tablets are and what are they used for.
2. What you need to know before you take Propafenone Hydrochloride tablets
3. How to take Propafenone Hydrochloride tablets
4. Possible side effects
5. How to store Propafenone Hydrochloride tablets
6. Contents of the pack and other information

#### **1. What Propafenone Hydrochloride tablets are and what are they used for**

Propafenone belongs to a group of medicines called anti-arrhythmic agents.

Propafenone is used for the following:

- to slow down the heart rate and help to regulate the heartbeat
- to treat and prevent arrhythmias (abnormal heart rhythms).

#### **2. What you need to know before you take propafenone hydrochloride tablets**

##### **Do not take propafenone hydrochloride tablets:**

- if you are allergic (hypersensitive) to propafenone hydrochloride or any of the other ingredients of this medicine (see section 6).
- if you suffer from a heart rhythm disorder called Brugada syndrome which causes you to have a potentially life-threatening heart rhythm.
- if you have had a heart attack within the last 3 months.
- if you suffer from heart failure or any heart problems other than abnormal heart rate/heart rhythm.
- if you have an unusually slow heart rate or low blood pressure (hypotension).
- if you suffer from breathing problems, such as chronic bronchitis or emphysema (sometimes known as COPD).
- if you have been told you that you have an imbalance of potassium or sodium in your blood.
- if you suffer from myasthenia gravis which causes muscle weakness
- if you are taking ritonavir (antiviral agents)

Propafenone Hydrochloride tablets are not suitable for children.

##### **Warnings and precautions:**

Talk to your doctor or pharmacist before using Propafenone hydrochloride tablets. Especially if you:

- are pregnant or planning to become pregnant or breast feeding.

- suffer from any breathing problems, such as asthma
- have been told that you have a disturbance in the salts (e.g. sodium or potassium) in your blood
- have a heart pacemaker.
- suffer from liver or kidney disease
- Tell your surgeon or dentist that you are taking propafenone hydrochloride tablets if surgery is planned. It may affect the anaesthetic used.

### **Other medicines and Propafenone Hydrochloride tablets**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

*Tell your doctor if you are using or have recently used:*

- Any other medicines used to treat heart conditions, angina and high blood pressure, or medicines that may impact the heart rate including:
  - beta blockers (e.g. propranolol, metoprolol)
  - amiodarone,
  - digoxin,
  - quinidine
- Medicines used to treat depression (e.g. amitriptyline, dothiepin, desipramine, venlafaxine, fluoxetine, paroxetine)
- Antibiotic and antifungal medicines (e. g. erythromycin ,rifampicin, ketoconazole)
- Medicines used to prevent organ transplant rejection (cyclosporin)
- Local anaesthetic medicines for dental surgery, or other minor surgical procedures (e.g. lidocaine)
- Medicines used for thinning blood (anticoagulant medicines e.g. warfarin)
- Other medicines used to treat stomach ulcers (cimetidine)
- Medicines for asthma (e.g. theophylline)
- Medicines used for prevention and treatment of nausea and vomiting ( e.g. tropisetron or dolasetron)
- Antihistamine to treat allergy (e.g. mizolastine )
- Medicines for epilepsy or seizures (e.g. phenobarbital )
- Cyclosporine (an immunosuppressant, used after transplant operations, or in the treatment of arthritis or psoriasis)
- Ritonavir (an antiviral medicine used in the treatment of HIV) – you must not use this medicine with Propafenone hydrochloride tablets

### **Propafenone Hydrochloride tablets with food or drink**

Propafenone hydrochloride tablets should not be taken with grapefruit juice. They should be taken after food, with some water.

### **Other important information**

- If you need to have an operation it is important to tell the surgeon or dentist, Propafenone hydrochloride may affect the anaesthetic or other treatments used.
- If you have a pacemaker, it may need to be altered.
- Propafenone hydrochloride tablets are not suitable for children.
- Your doctor may perform ECGs and blood pressure monitoring prior to and during treatment to monitor your individual dose.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The safety of propafenone for use during pregnancy has not been established. Hence, it should be taken only if your doctor advises to do so.

You should not take propafenone hydrochloride tablets if you are breast-feeding

### **Driving and using machines**

Propafenone hydrochloride tablets can cause blurred vision, dizziness, tiredness and low blood pressure in some people. Do not drive, operate machinery or do anything that requires you to be alert until you know how the tablets affect you.

**Propafenone Hydrochloride tablets contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

**3. How to take Propafenone Hydrochloride tablets**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow your tablets with some water without chewing them. It is best to take them after food.

The number of tablets that you will need to take will be decided by your doctor. This may be between one propafenone hydrochloride 150 mg tablet three times a day to one propafenone hydrochloride 300 mg tablet three times a day.

You may need a lower dose of propafenone hydrochloride tablets if you are elderly, if you have problems with your kidneys or liver, or if you have a low bodyweight.

**Use in children**

Propafenone hydrochloride tablets are not recommended for children.

**If you take more Propafenone Hydrochloride tablets than you should**

It is important to stick to the dose on the label of the medicine. If you or someone else swallows several of these tablets all together, contact your doctor or nearest hospital emergency department immediately. Always take any tablets left over with you and also the box, as this will allow easier identification of the tablets.

**If you forget to take Propafenone Hydrochloride tablets**

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose do not take a double dose to make up for a forgotten dose, just carry on as before.

**If you stop taking Propafenone Hydrochloride tablets**

It is important that you keep taking these tablets until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the tablets without your doctor's advice, your condition may get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Tell your doctor or pharmacist immediately if you experience any of the following:**

- 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 eyes, as these may be a sign of liver 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.

Other side effects with , propafenone hydrochloride tablets may include:

Very Common side effects (occurring in more than 1 in 10 users):

- Dizziness
- Irregular (slow or fast) heart beat
- Heart palpitations (being aware of your heart beat)

Common side effects (occurring in 1 to 10 users in 100):

- 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 tired or weak
- Fever

Uncommon side effects (occurring in 1 to 10 users in 1000):

- Reduction in blood platelets, which increases risk of bleeding or bruising
- 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 (passing wind/gas)
- Redness of skin and itchy skin
- Impotence
- Heart rhythm disorders such as irregular heart beat

The following are side effects with an unknown frequency:

- Severe reduction in the number of white blood cells which makes infections more likely
- Confusion
- Seizures
- Tremor (feeling shaky)
- Rigidity (stiffness)
- Restlessness
- Life threatening irregular heart beat
- Heart problems which can cause shortness of breath or ankle swelling

- A fall in the blood pressure on standing up which may cause dizziness, light headedness or fainting
- Liver cell damage, blockage of the flow of bile from the liver (cholestasis), inflammation of the liver (hepatitis), yellowing of the skin or whites of the eyes (jaundice)
- Retching
- Lupus-like syndrome (an allergic condition which causes joint pain, skin rashes and fever)
- A reversible drop in the sperm count has occasionally been reported with high doses.
- Pustular skin eruptions.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance; Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Propafenone Hydrochloride tablets**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the blister and carton. The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original carton to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Propafenone Hydrochloride tablets contains**

The active substance is propafenone hydrochloride.

Each film-coated tablet contains 150mg, or 300mg of propafenone hydrochloride.

Other ingredients are maize starch, hypromellose E5, microcrystalline cellulose, Croscarmellose sodium, magnesium stearate, talc, titanium dioxide and macrogol 6000.

#### **What Propafenone Hydrochloride tablets looks like and contents of the pack**

Propafenone hydrochloride 150mg film-coated tablets are white, round shaped, biconvex, film coated tablets plain on both sides.

Propafenone hydrochloride 300mg film-coated tablets are white to off white, round shaped, biconvex, film-coated tablets with a score line on one side and plain on the other side. The tablet can be divided into equal halves.

Propafenone hydrochloride 150mg film-coated tablets are supplied in Aluminium//PVC/PVdC blisters containing 20, 50, 90 and 100 tablets. Propafenone hydrochloride 300mg film-coated tablets are supplied in Aluminium//PVC/PVdC blisters containing 20, 50, 60 and 100 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder**

Accord Healthcare Ireland Limited,  
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##### **Manufacturer**

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