

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROPAFEN

300mg Film-coated Tablets

PROPAFENONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What PROPAFEN is and what it is used for
2. Before you take PROPAFEN
3. How to take PROPAFEN
4. Possible side effects
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1. WHAT PROPAFEN IS AND WHAT IS IT USED FOR

PROPAFEN belongs to a group of medicines called anti-arrhythmic agents. PROPAFEN 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. BEFORE YOU TAKE PROPAFEN

Do not take PROPAFEN tablets if you:

- are allergic (hypersensitive) to PROPAFEN or any other ingredients in the tablets.
- suffer from heart failure or any heart problems other than abnormal heart rhythm.
- have been diagnosed as having the condition known as myasthenia gravis?

PROPAFEN tablets are not suitable for children.

Take special care with PROPAFEN tablets and consult your doctor if you:

- are pregnant or planning to become pregnant or breast feeding.
- have an unusually slow heart rate or hypotension (low blood pressure)
- 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

Take special care with PROPAFEN tablets

- If you have a heart pacemaker.

Tell your surgeon or dentist that you are taking PROPAFEN tablets if surgery is planned. It may affect the anaesthetic used.

Taking other medicine

Take special care with PROPAFEN tablets and consult your doctor if you are taking:

- other medicines that affect the activity of the heart such as amiodarone, digoxin, quinidine
- tablets to prevent blood clots (e. g. warfarin)
- antibiotics (e. g. erythromycin or rifampicin)
- any of the group of medicines known as beta-blockers (these are used to treat high blood pressure)
- any antiviral agents (e. g. ritonavir)
- any of the group of medicines known as major tranquillisers, or an antidepressant of the tricyclic or related group (e.g. amitriptyline, dothiepin, desipramine)
- any other antidepressants, such as venlafaxine, fluoxetine, paroxetine
- taking cimetidine (an ulcer medicine)
- cyclosporin (an immunosuppressant, used after transplant operations, or in the treatment of arthritis or psoriasis)
- theophylline (used in the treatment of asthma)
- ketoconazole (an antifungal agent)
- tropisetron or dolasetron (prevention and treatment of nausea and vomiting)
- mizolastine (antihistamine to treat allergy)
- phenobarbital (for epilepsy)

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

Taking PROPAFEN tablets with food or drink

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

Pregnancy and breast-feeding

The safety of PROPAFEN for use during pregnancy has not been established. Hence, it should be taken only if your doctor advises to do so. Please ask your doctor or pharmacist for advice before taking any medicine.

You should not take PROPAFEN tablets if you are breast-feeding

Driving and using machines

PROPAFEN 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.

3. HOW TO TAKE PROPAFEN

Follow your doctor's directions about when and how to take your tablets and look at the label on the carton. Your pharmacist will also help if you are not sure.

Swallow your tablets with some water. 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 PROPAFEN 150 mg tablet three times a day to one PROPAFEN 300 mg tablet three times a day.

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

PROPAFEN tablets are not recommended for children.

If you take more PROPAFEN 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 PROPAFEN 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 PROPAFEN 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PROPAFEN tablets can have side effects although not everybody gets them.

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

☒ Allergic reactions such as skin reddening, itching or a rash. Allergic reactions may affect the liver. Allergic reactions are reversible if the treatment is stopped. These effects are rare.

☒ Bruise easily or if you develop a very sore throat with a high fever. Treatment may affect the blood. These effects are reversible if the treatment is stopped and have been reported in very rare cases.

The following side effects have been reported: - Occasionally:

- constipation or diarrhoea
- bloating
- feeling sick
- retching
- vomiting
- loss of appetite
- abdominal pain
- fainting
- ataxia (problems with coordination)
- chest pain
- dizziness
- headaches
- blurred vision
- feeling tired
- dry mouth
- a bitter taste in the mouth
- hypotension (low blood pressure) or unwanted effects on the heart rate

Very rarely:

- restlessness
- nightmares
- sleep disorders
- anxiety
- breathlessness or wheezing.
- confusion
- shaking
- stiffness
- seizures

A reversible drop in the sperm count has occasionally been reported with high doses.

Abnormal liver function blood tests, damage or inflammation of liver cells, and jaundice, have been reported in patients taking PROPAFEN tablets.

Vertigo (spinning sensation), paresthesia (tingling, pins and needles) and lupus syndrome (symptoms include facial rash, joint pain, muscle disorder and fever) have also been reported.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPAFEN

- Keep out of the reach and sight of children.
- Do not use PROPAFEN tablets 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.