

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Flecainide 50 mg Tablets **Flecainide 100 mg Tablets**

flecainide acetate

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. See section 4.

What is in this leaflet

1. What Flecainide is and what it is used for
2. What you need to know before you take Flecainide
3. How to take Flecainide
4. Possible side effects
5. How to store Flecainide
6. Contents of the pack and other information

1. What Flecainide is and what it is used for

Flecainide belongs to a group of medicines called antiarrhythmics which can be used to control the rate and rhythm of the heart.

Flecainide tablets are used to treat:

- Arrhythmias (irregular heart beat such as Wolff-Parkinson White Syndrome)
- Tachycardia (fast heart beat)
- Fibrillation (rapid contractions of muscles in the heart).

2. What you need to know before you take Flecainide

Do not take Flecainide:

- if you are allergic to flecainide or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you are using class 1 anti-arrhythmics (e.g., quinidine, procainamide)
- if you have had heart problems such as heart failure, heart attack, heart valve or conduction problems - your doctor will study your medical history
- if you have been told you have an electrolyte imbalance (altered blood salts)
- if you have cardiogenic shock
- if you suffer from known Brugada syndrome

Warnings and precautions

Talk to your doctor or pharmacist before taking Flecainide if you have any of the following conditions:- if you have liver disease

- if you have a pacemaker
- if you have or have had heart failure
- if you have an enlarged heart
- if you have ever had a heart attack
- if you have or have had angina

- if you have heart disease
- if you have rapid and irregular heart beat after surgery
- if you have severe hepatic disease
- if you have impaired renal function

You will be monitored to check your fluid balance and salts.

Children

Flecainide is not recommended for children under 18 years as there is not enough evidence of its use.

Other medicines and Flecainide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor or pharmacist if you are already taking or have taken any of the following medicines as they may interact with flecainide:

- Digoxin (used to treat heart failure)
- Drugs that affect the heart such as beta blockers or verapamil (used to treat high blood pressure)
- Other anti-arrhythmic drugs such as amiodarone
- Antidepressants such as fluoxetine, paroxetine, reboxetine and tricyclic antidepressants
- Drugs for epilepsy such as phenytoin, Phenobarbital, carbamazepine
- Clozapine (used to treat mental illness)
- Antihistamines such as mizolastine or terfenadine (used to treat hayfever and allergies)
- Quinine (used to treat and prevent malaria)
- Ritonavir (used to treat HIV [AIDS])
- Diuretics (water tablets)
- Cimetidine (an ulcer healing drug)
- Bupropion (an anti-smoking aid)
- Terbinafine (an antifungal drug)

It may still be all right for you to be given Flecainide and your doctor will be able to decide what is suitable for you.

Flecainide with food and drink

Dairy products may affect the intake of flecainide in children and newborns. It is not known if this may apply to adults. Talk to your pharmacist or doctor for advice.

Pregnancy and breast-feeding

You should not take Flecainide while pregnant or breast-feeding unless your doctor tells you to.

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.

Driving and using machines

It is advisable not to drive, operate machinery or do anything that requires you to be alert until you know how Flecainide affects you. This is because Flecainide can cause blurred vision or dizziness in some people.

Flecainide 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 Flecainide

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

Your doctor will monitor you regularly. Your doctor has decided which dose is best for you. Follow your doctor's instructions and do not change the dose yourself. Treatment usually starts in hospital as the doctor will perform an ECG (electrical tracing of the heart) and monitor your blood flecainide levels.

Adults

The usual dose is 100 mg twice a day up to a maximum dose of 400 mg per day.

Some patients, particularly those with supra-ventricular tachycardia will be adequately controlled on 50 mg twice daily.

Your dose will be adjusted so that you benefit from the lowest dose.

Elderly and patients with liver or kidney disease Elderly patients or patients with liver or kidney disease may need a lower dose.

Patients with liver or kidney disease may need a reduced dose.

Use in children and adolescents

Flecainide is not recommended for children and adolescents under 18 years.

How to take

Swallow the tablets with a glass of water.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole (100 mg only).

If you take more Flecainide than you should

It is unlikely that you will be given the wrong dose of Flecainide as treatment is usually given in hospital.

If you forget to take Flecainide

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten tablet.

If you stop taking Flecainide

Do not suddenly stop taking your medicine as you may experience side effects. Speak to your doctor first.

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.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Weakness, tiredness, fever, swelling, missed heart beats, slow heart beat, heart failure, chest pain, low blood pressure, heart attack, fast or irregular heart beat, rash, hair loss, light sensitivity, feeling sick, vomiting, tummy pain, anorexia (loss of appetite), constipation, diarrhoea, indigestion, flatulence (wind).

Also, raised liver enzymes and changes in the numbers of blood cells (your doctor can detect these with a blood test), yellow eyes and skin, itching, liver failure, dizziness, light-headedness, headache,

muscle weakness and cramps, muscle pain, pins and needles, lack of co-ordination, joint pain, flushing, numbness, and increased sweating.

Sleepiness, fainting, ringing in the ears, tremor, spinning sensation, double vision, blurring of vision, corneal deposits (spots on the eye surface), breathlessness, inflammation of the lungs, depression, anxiety, confusion, hallucination and sleeplessness.

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 HPRAs Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flecainide

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 carton and blister or container after 'Expiry date:'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 to protect the environment.

6. Contents of the pack and other information

What Flecainide contains

- The active substance is flecainide acetate. Each tablet contains either 50 mg or 100 mg of flecainide acetate.
- The other ingredients are magnesium stearate, croscarmellose sodium and microcrystalline cellulose.

What Flecainide looks like and contents of the pack

The tablets are white and convex. The 50 mg tablets are marked 'FC' over '50' and the 100 mg tablets are marked 'FC' scoreline '100', on one side. On the other side the tablets are marked 'G'.

Flecainide 50 mg tablets are available in plastic containers and blister packs of 20, 30, 50, 60 and 100 tablets.

Flecainide 100 mg tablets are available in plastic containers and blister packs of 20, 30, 40, 50, 60 and 100 tablets.

Not all pack sizes may be marketed.

Product Authorisation Holder

Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands

Manufacturers

McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Generics [UK] Ltd, Station Close, Potters Bar, Herts EN6 1TL, UK.

Mylan Hungary Kft
H-2900 Komárom
Mylan utca 1
Hungary

This leaflet was last revised in October 2021.