

PACKAGE LEAFLET

Package leaflet: Information for the patient

Flecainide Acetate 50 mg Tablets **Flecainide Acetate 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 antiarrhythmic agents. Flecainide is used to treat an irregularity in the heartbeat (known as an arrhythmia). It works by correcting irregular heartbeats to a normal rhythm.

2. What you need to know before you take Flecainide

Do not take Flecainide

- if you are allergic to flecainide acetate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from heart failure or some types of heart rhythm disorders
- if you suffer from heart valve disease
- if you have a history of heart attacks
- if you have low blood pressure or a slow beating heart
- if you have a serious heart condition called cardiogenic shock which causes rapid breathing, weakness, looking pale, confusion and can lead to a loss of consciousness
- if you have a heart condition called Brugada Syndrome, which causes you to have a potentially life-threatening heart rhythm disorder
- if you are already taking Disopyramide to regulate your heartbeat

Warnings and precautions

Talk to your doctor or pharmacist before taking Flecainide:

- if you know you have high or low levels of salt (such as potassium) in your blood
- if you suffer from liver or kidney problems
- if you have a heart rhythm disorder called 'sick sinus syndrome'
- if you have a pacemaker
- if you suffer from an enlarged heart, or some types of heart disease.

Other medicines and Flecainide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or the following:

- diuretics (water tablets) e.g. furosemide
- corticosteroids for inflammatory conditions such as arthritis e.g. prednisolone
- laxatives to treat constipation
- other medicines used to regulate your heartbeat e.g. digoxin, quinidine, beta-blockers (e.g. atenolol, propranolol), amiodarone, verapamil
- anticonvulsants, for epilepsy e.g. phenytoin, phenobarbital, carbamazepine
- cimetidine, to treat stomach ulcers
- antivirals e.g. ritonavir, fixed-combination products containing ritonavir
- anti-malarials e.g. quinine
- antihistamine e.g. mizolastine, terfenadine
- antidepressants e.g. fluoxetine, paroxetine, reboxetine and tricyclic anti-depressants such as imipramine
- bupropion, used as an antidepressant and an antismoking aid
- antifungals e.g. terbinafine
- antipsychotics to treat some mental illnesses e.g. clozapine

Flecainide with food and drink

Dairy products like milk, infant formula and possibly yoghurt have been shown to reduce the absorption of flecainide acetate in children and infants. It is not known if this may apply to adults. Talk to your pharmacist or doctor for advice.

Pregnancy and breast-feeding

Flecainide **should not** be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby. If your doctor does decide to give you Flecainide, you will be monitored closely during your pregnancy. 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 any medicine.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine.

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 choose the dose which best suits your condition.

Adults

The usual starting dose is either 50 mg or 100 mg twice daily. If necessary, your doctor will increase this starting dose to a maximum dose of 400 mg daily.

When your condition has been brought under control your doctor may reduce your dose to the lowest dose you need.

Your doctor may wish to start flecainide treatment in hospital where he/she will perform regular ECGs (electrical tracing of the heart) and monitor your blood flecainide levels. Your doctor may also wish to perform these tests if or when he/she alters the dose of flecainide you are taking or if you have switched from a different formulation (e.g. from an injection of flecainide).

Patients with liver or kidney problems

Your doctor may give you a lower dose and will closely monitor you.

Patients with a pacemaker

If you have a pacemaker your dose should not exceed 100 mg twice daily. Your doctor will closely monitor you.

Elderly

If you are elderly, your doctor may prescribe a lower starting dose for you.

Children

Flecainide is not recommended for use in children under 12 years

Flecainide tablets should be taken orally.

If you take more Flecainide than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you.

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 dose.

If you stop taking Flecainide

If you suddenly stop taking Flecainide you may experience side effects. Speak to your doctor first before stopping this medicine.

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.

If you experience the following, stop taking Flecainide tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

Common side effects (may affect up to 1 in 10 people)

- fast or irregular heart beat.

Rare side effects (may affect up to 1 in 1,000 people)

- inflammation of the lungs which can cause weakness, breathlessness, cough and raised temperature (pneumonitis)
- changes in liver function with or without yellowing of the skin or whites of the eyes (jaundice), usually reversible on stopping treatment
- fits (convulsions).

Very rare side effects (may affect up to 1 in 10,000 people)

- worsening of eyesight.

Not Known (frequency cannot be estimated from available data)

- heart block which can cause light-headedness, fainting and irregular heart rhythm
- slower heart rhythm, dangerously fast heart rhythm
- heart attack
- a heart disease called sinus arrest
- chest pain
- scarring of the lungs or lung disease which causes shortness of breath

- heart failure which can cause shortness of breath and swelling of the feet or legs due to fluid retention.

The following side effects have also been reported:

Very common side effects (may affect more than 1 in 10 people):

- feeling giddy, dizzy or lightheaded
- blurred or double vision

Common side effects (may affect up to 1 in 10 people):

- breathlessness, difficulty breathing
- weakness
- tiredness
- fever
- excessive fluid in the body (swelling).

Uncommon side effects (may affect up to 1 in 100 people):

- reduction in red blood cell count, which may make the skin pale and cause weakness or breathlessness
- reduction in white blood cell count, which makes you prone to infections
- reduction in platelet count, which can make you bleed or bruise more easily than normal
- feeling or being sick
- constipation
- stomach pain or discomfort
- reduced appetite
- diarrhoea
- indigestion
- wind (flatulence)
- inflammation of the skin due to allergies, including rash
- hair loss.

Rare side effects (may affect up to 1 in 1,000 people):

- depression
- confusion or anxiety
- loss of memory
- difficulty sleeping or sleepiness
- seeing, hearing or feeling things that are not there (hallucinations)
- nervousness
- numbness or weakness of the arms and legs
- tingling, pins and needles
- sudden uncontrollable or abnormal body movements, shaking
- decreased feeling or sensitivity, especially in the skin
- increased sweating
- fainting
- redness of the skin (flushing)
- headache
- ringing in the ears
- a nettle-like rash, hives.

Very rare side effects (may affect up to 1 in 10,000 people):

- dry mouth or taste changes
- sensitivity of the skin to light
- painful, swollen joints or muscle pain
- impotence
- raised levels of certain antibodies, which may cause inflammation.

Not Known (frequency cannot be estimated from available data):

- low blood pressure
- palpitations
- liver disease.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google

Play or Apple App Store.

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 Flecainide after the expiry date which is stated on the carton/**bottle/blister** after EXP. 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 protect the environment.

6. Contents of the pack and other information

What Flecainide contains

The active substance is flecainide as flecainide acetate 50 mg or 100 mg.

The other ingredients are magnesium stearate, croscarmellose sodium and microcrystalline cellulose.

What Flecainide looks like and contents of the pack

Your medicine comes as a white round tablet. The 50 mg tablets are marked 'FC' over '50' on one side and 'G' on the other. The 100 mg tablets are marked 'FC' breakline '100' on one side and 'G' on the other. The 100 mg tablets can be divided into equal doses.

Flecainide Acetate Tablets are available in blisters or plastic bottles (with an optional filler) of 20, 30, 50, 60 and 100 tablets and plastic bottles of 500 tablets. The 100 mg tablets are also available in blisters or plastic bottles (with an optional filler) of 40 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturer:

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This leaflet was last revised in: December 2020