

Package leaflet: Information for the user

Flecainide Acetate 50 mg and 100 mg Tablets (flecainide acetate)

Read all of this leaflet carefully before you starts 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

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1. What Flecainide Acetate tablets is and what it is used for

Flecainide Acetate tablets belong to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart.

Flecainide Acetate tablets are used to treat:

- Arrhythmias (irregular heart beat)
- Tachycardia (heart beating too fast)
- Atrial fibrillation (rapid contractions of muscles in the heart).

It is important for your doctor to treat these conditions quickly and effectively in order to prevent more serious heart problems from developing.

There are two strengths of tablet available, 50 mg and 100 mg.

2. What you need to know before you take Flecainide Acetate tablets

Do not take Flecainide Acetate tablets if you:

- are allergic to flecainide acetate or any of the other ingredients of this medicine (listed in section 6)
- have heart failure
- have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
- have heart block (your heart misses beats)
- have long-standing atrial fibrillation (rapid contractions of muscles in the heart)
- have or have ever had any heart problems including problems with the valves in your heart or conduction problems
- have sinus node dysfunction (a specific condition where your heart beats abnormally)
- have had a myocardial infarction (heart attack)

- have Brugada Syndrome, a genetic disease that causes severe disturbances of the rhythm of the heart and may lead to sudden death in apparently healthy individuals.
- are pregnant or breast-feeding.

If any of the above applies to you tell your doctor or pharmacist.

Before you take Flecainide Acetate tablets your doctor may check:

- Your fluid levels are correct
- Your liver and kidney functions.

This is to check that Flecainide Acetate tablets are right for you and to help the doctor calculate the dose you need.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flecainide Acetate tablets if you:

- have high blood pressure
- have angina (chest pains)
- have heart disease
- have kidney disease or kidney problems
- have liver disease or liver problems
- wear a pacemaker.

Children

Flecainide acetate tablets are not recommended for children under 12 years of age.

Other medicines and Flecainide Acetate tablets

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

- Any other medicine used to treat heart arrhythmias or heart problems such as cardiac glycosides, beta-blockers, verapamil, propranolol or amiodarone
- Medicines to treat high blood pressure
- Antidepressants (medicines used to treat depression), such as tricyclic antidepressants, fluoxetine, paroxetine or reboxetine
- Anticonvulsants (medicines used to prevent epileptic fits) such as phenytoin, phenobarbital or carbamazepine
- Antipsychotics (medicines to treat mental illness) such as clozapine
- Antihistamines (medicines to treat allergic reactions) such as mizolastine or terfenadine
- Quinine (medicine to treat malaria)
- Medicines to treat HIV such as ritonavir, lopinavir or indinavir
- Diuretics (water tablets)
- Cimetidine (medicine to treat stomach ulcers)
- Bupropion (a medicine to help stop you smoking)

These medicines may interfere with your treatment.

Pregnancy, breast-feeding and fertility

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:

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

Information about ingredient of Flecainide tablets

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

3. How to take Flecainide Acetate tablets

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

Important:

Your doctor will choose the dose that is right for your condition. Usually your treatment with Flecainide Acetate tablets will be started in hospital.

If you have switched from a different formulation (e.g. from an injection of flecainide) your doctor should do so with caution and monitor you closely.

Adults:

Supraventricular arrhythmias (Irregular heart beat that starts in the upper chambers of your heart)

- Flecainide Acetate 50mg tablets: The recommended dose is one tablet twice a day.
- Flecainide Acetate 100mg tablets: The recommended dose is half a tablet twice a day.

Your doctor may prescribe up to a total dose of 300 mg daily (3 x 100 mg tablets or 6 x 50 mg tablets).

Ventricular arrhythmias (Irregular heart beat that starts in the lower chambers of your heart)

- Flecainide Acetate 50mg tablets: The recommended dose is two tablets twice a day.
- Flecainide Acetate 100mg tablets: The recommended dose is one tablet twice a day.

Your doctor may prescribe up to a total dose of 400 mg daily (4 x 100 mg tablets or 8 x 50 mg tablets).

The elderly and patients with kidney or heart problems:

- For elderly patients, and patients with kidney or heart problems, the doctor may tell you to take a lower dose.

While you are taking this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

Use in Children:

- Flecainide Acetate tablets are not recommended for children under 12 years of age, However, dairy products such as milk, infant formula and possibly yoghurt, may reduce how much flecainide acetate is absorbed in children and infants.

If you take more Flecainide Acetate tablets than you should

If you accidentally take too much, immediately go to the nearest hospital casualty department.

If you forget to take Flecainide Acetate tablets

Do not take a double dose to make up for a forgotten dose.
Simply take the next dose as planned.

If you stop taking Flecainide Acetate tablets

Do not stop taking Flecainide Acetate tablets without first talking to your doctor.
If you have any further questions about 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.

Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

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

- Your heartbeat changes; it starts to pound, or it gets faster or slower
- You have chest pain
- You become breathless or have other breathing problems
- You have a fever, become flushed or sweat
- You faint or you feel faint

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

- You have ringing in your ears
- Your skin and eyes begin to go yellow (jaundice)
- You have fits (convulsions).

Other side effects (how often they happen is unknown):

- heart attack
- cardiac failure/arrest (loss of breathing, and consciousness and loss of heart function)

Other side effects include the following, if they get serious, please tell your doctor:

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

- Dizziness
- Double or blurred vision

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

- Feeling weak or tired
- Lack of energy and strength
- Swelling (fluid retention)

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

- Blood disorders (reduced red and white blood cell count and reduced platelet count)
- Feeling or being sick
- Constipation
- Stomach pain or indigestion
- Loss of appetite
- Diarrhoea
- Wind

- Feeling bloated
- Red, itchy or swollen skin rash
- Hair loss

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

- Vertigo (feeling like the room is spinning)
- Confusion and hallucinations
- Depression
- Feeling anxious (worried)
- Forgetfulness
- Difficulty sleeping
- Numbness, tingling, tickling, prickling or burning sensation of the skin
- Unsteady walking, uncontrolled movements or poor coordination, difficulty speaking
- Reduced sense of touch
- Excessive sweating and flushed skin
- Shaking (tremors)
- A strong desire to sleeping or sleep for long periods
- Headache

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

- Small cloudy spots on the eyeball
- Sensitivity of the skin to sunlight

Other side effects (how often they happen is unknown):

- Lung disease and scarring of the lungs
- Liver disease
- Joint pain and muscle pain

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 Yellow Card Scheme, Website: 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 Acetate tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 Acetate tablets contain

- The active substance is flecainide acetate. Each 50 mg tablet contains 50 mg of flecainide acetate. Each 100 mg tablet contains 100 mg flecainide acetate.

- The other ingredients are silicified microcrystalline cellulose, croscarmellose sodium, maize starch and magnesium stearate.

What Flecainide Acetate tablets looks like and contents of the pack

Flecainide Acetate 50 mg tablets :

White to off white, circular, biconvex, tablets debossed with F1 on one side and plain on other side with an approximate diameter of 6.5 mm.

Flecainide Acetate 100 mg tablets:

White to off white, circular, biconvex, tablets debossed with F & 2 separated by score line on one side and plain on other side with an approximate diameter of 8.8 mm. The tablet can be divided into equal halves.

Both strengths of Flecainide Acetate tablets available in blister packs of 20, 28, 30, 40, 50, 56, 60, 84, 90, 100 112, 120, 168 and 180 tablets.

Not all pack sizes may be marketed

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