

Package leaflet: Information for the patient

Flecainide acetate 25 mg/5 ml oral solution

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.

The name of your product is Flecainide acetate 25 mg/5 ml oral solution, but it will be referred to as Flecainide oral solution throughout this leaflet.

What is in this leaflet

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

1. What Flecainide oral solution is and what it is used for

Flecainide oral solution belongs to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart.

Flecainide oral solution is used to treat:

- Arrhythmias (irregular heartbeat)
- 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.

2. What you need to know before you take Flecainide oral solution

Do not take Flecainide oral solution 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 oral solution your doctor may check:

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

This is to check that Flecainide oral solution is 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 oral solution 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 oral solution is not recommended for children under 12 years of age.

Other medicines and Flecainide oral solution

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

- Any other medicine used to treat heart arrhythmias or heart problems, such as cardiac glycosides (e.g. digoxin), beta-blockers (e.g. propranolol, metoprolol, atenolol, bisoprolol), verapamil or amiodarone
- Medicines to treat high blood pressure
- Antidepressants (medicines used to treat depression) such as tricyclic antidepressants (e.g. clomipramine, amitriptyline, nortriptyline, doxepin), 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) such as furosemide, hydrochlorothiazide, spironolactone or acetazolamide
- Cimetidine (medicine to treat stomach ulcers)
- Bupropion (a medicine to help you stop smoking).

These medicines may interfere with your treatment.

Flecainide oral solution with food and drink

Dairy products (milk, infant formula and possibly yoghurt) may reduce the absorption of flecainide in children and infants. Flecainide is not approved for use in children below the age of 12 years, however flecainide toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings.

Flecainide should be taken on an empty stomach or at least one hour before a meal.

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.

Flecainide acetate 25 mg/5 ml oral solution contains sodium benzoate and sodium.

This medicine contains 4.0 mg sodium benzoate in each 5 ml.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3. How to take Flecainide oral solution

Always take Flecainide oral solution 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 oral solution 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 heartbeat that starts in the upper chambers of your heart):

- The recommended dose is 50 mg (10 ml of the oral solution) twice a day.

Your doctor may prescribe up to a total dose of 300 mg (60 ml of the oral solution) daily.

Ventricular arrhythmias (irregular heartbeat that starts in the lower chambers of your heart):

- The recommended dose is 100 mg (20 ml of the oral solution) twice a day.

Your doctor may prescribe up to a total dose of 400 mg (80 ml of the oral solution) daily.

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 oral solution is not recommended for children under 12 years of age.

How to take Flecainide oral solution

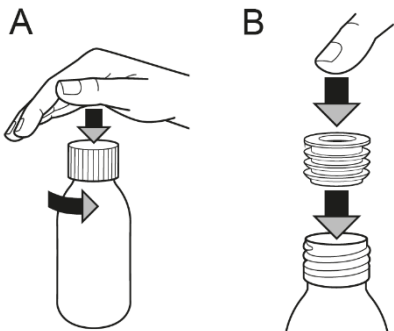
Take this medicine by mouth.

Flecainide should be taken on an empty stomach or at least one hour before a meal.

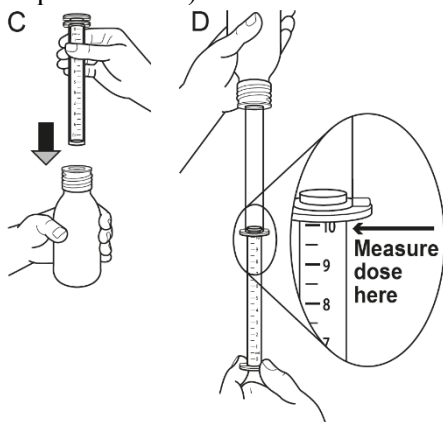
Liquid flecainide formulations may have a local anaesthetic effect on the mouth so your mouth may feel numb after taking Flecainide oral solution. You should not eat until any anaesthetic effect has disappeared.

A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a “Press-In” Bottle Adapter (PIBA) are provided with the product.

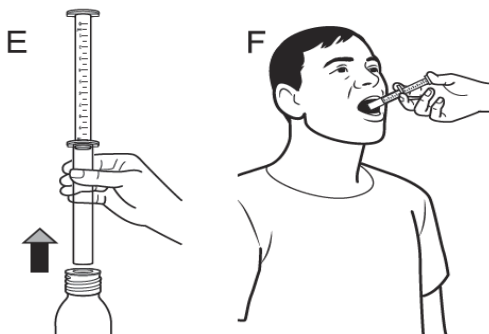
1. Open the bottle and at first use insert the “Press-In” Bottle Adapter (PIBA) (see pictures A-B).



2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).



3. Remove the filled syringe from the bottle in the upright position (see picture E).
4. Discharge the syringe contents into the mouth (see picture F). Repeat steps 2 to 4 as needed to achieve the required dose.



5. Replace the cap on the bottle (PIBA remains in place).

6. The oral syringe must be rinsed thoroughly with water after each use by taking the two parts of syringe apart. Allow the parts to air dry afterwards.

If you take more Flecainide oral solution than you should

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

If you forget to take Flecainide oral solution

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

If you stop taking Flecainide oral solution

Do not stop taking Flecainide oral solution without first talking to your doctor.

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.

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 sleep or sleeping 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
- Numbness in the mouth*

*This adverse effect relates specifically to the liquid formulation.

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 oral solution

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 label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Store in the original bottle in order to protect from light.

After first opening use within 1 month.

Do not use this medicine if you notice particles or small crystals in the solution.

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 oral solution contains

- The active substance is flecainide acetate.
- Each 5 ml of Flecainide oral solution contains 25 mg of flecainide acetate, equivalent to 21.8 mg of flecainide.
- The other ingredients are: sodium benzoate (E211), sucralose (E955), cherry flavour, citric acid (E330) and purified water.

What Flecainide oral solution looks like and contents of the pack

Flecainide oral solution is a clear, colourless solution with characteristic cherry odour. It is supplied in amber, type III glass bottles, safely closed with a child-resistant, screw cap with tamper evident closure. Each bottle contains 300 ml of this medicine.

A CE marked 10 ml oral syringe of 0.5 ml graduations along with a press-in bottle adapter are also provided.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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