

Flecainide Sandoz

Tablets 50 mg & 100 mg

Flecainide acetate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Flecainide Sandoz.

This leaflet answers some common questions about Flecainide Sandoz. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.ebs.tga.gov.au.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Flecainide Sandoz against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Flecainide Sandoz is used for

Flecainide Sandoz contains flecainide acetate. It belongs to a group of medicines called antiarrhythmics, which slow down the impulses that cause the heart to beat in an irregular or abnormal way.

Flecainide Sandoz is used to treat a heart condition called arrhythmia, which is an irregular or abnormal heart beat.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

Flecainide Sandoz is only available with a doctor's prescription.

Flecainide Sandoz is not addictive.

Before you take Flecainide Sandoz

Flecainide Sandoz is not suitable for everyone.

When you must not take it

Do not take Flecainide Sandoz if you:

- are allergic to any medicine containing flecainide acetate or any of the ingredients listed at the end of this leaflet
- have severe heart, liver or kidney disease unless your doctor says it is suitable for you.

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Flecainide Sandoz, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney, liver or heart problems
- abnormal levels of potassium in the blood
- anaemia or other blood disease

- any lung disease.

Tell your doctor if you have a pacemaker fitted.

Your doctor may prescribe a lower dose for you.

Do not take this medicine if you are pregnant or intend to become pregnant.

The safety of the use of this medicine in women who are pregnant or may become pregnant has not been established. Flecainide Sandoz is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

The active ingredient in Flecainide Sandoz passes into breast milk and there is a possibility that your baby may be affected. Flecainide Sandoz is not recommended for use during breast-feeding, unless you and your doctor have discussed the risks and benefits involved.

Use with caution if you are elderly.

Elderly persons may be more sensitive to the effects of the medicine and your doctor may prescribe a lower dose for you.

Do not give Flecainide Sandoz to children.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Flecainide Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you are taking Flecainide Sandoz.

Some medicines and Flecainide Sandoz may interfere with each other. These include:

- medicines used to treat high blood pressure, angina or other heart conditions (e.g. digoxin, beta blockers, calcium channel blockers and diuretics)
- other medicines used to treat irregular or abnormal heart beat (e.g. disopyramide, verapamil, amiodarone and lidocaine)
- certain medicines used to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine)
- cimetidine, used to treat stomach ulcers.

The above medicines may be affected by Flecainide Sandoz, or may affect how well it works. You may need different amounts of Flecainide Sandoz, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Flecainide Sandoz.

How to take Flecainide Sandoz

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Flecainide Sandoz you should take. The usual starting dose of Flecainide Sandoz is 50 to 100 mg every 12 hours. Your doctor may gradually increase this dose. The usual maximum dose is 300 mg per day, however some patients may need up to 400 mg per day.

Never change the dose yourself.

It is very important to follow your doctor's instructions exactly.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Flecainide Sandoz may not work as well and your problem may not improve.

When to take it

Flecainide Sandoz is usually taken twice a day.

Swallow the tablets with a full glass of water, before or after meals.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Do not stop taking it unless your doctor tells you to.

It is very important to follow your doctor's instructions exactly. Stopping this medicine suddenly may make your condition worse.

If you are unsure whether you should stop taking Flecainide Sandoz, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect. If you miss two or more doses, please talk to your doctor.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Flecainide Sandoz

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Flecainide Sandoz. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking Flecainide Sandoz.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may need to do blood tests and monitor your heart (e.g. ECG test).

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take Flecainide Sandoz to treat any other complaints unless your doctor tells you to.

Do not stop taking Flecainide Sandoz or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Flecainide Sandoz affects you.

It may cause dizziness, light-headedness, faintness or vision problems in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

If you continue to feel unwell, tell your doctor.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Flecainide Sandoz.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include a slow pulse and dizziness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Flecainide Sandoz.

Like all medicines, Flecainide Sandoz may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately if you notice any of the following and they worry you:

- dizziness or light-headedness
- vision problems, e.g. double vision, blurred vision, difficulty focusing, light sensitivity
- headache

- nausea or vomiting, loss of appetite
- fatigue, tiredness, weakness
- increased sweating, flushing, dry mouth
- fever, joint or muscle pain
- abdominal problems, e.g. constipation, abdominal pain, diarrhoea
- tremor, nervousness, sleepiness, insomnia (difficulty sleeping)
- co-ordination problems and difficulties in movement, e.g. tics
- skin problems, e.g. tingling, decreased sensitivity or numbness, rash, itching
- coughing
- ringing in the ears
- urination problems
- oedema (build-up of fluid in the tissues).

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heartbeat, chest pains or fainting.

These may be serious side effects. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- severe light-headedness or dizziness
- difficulty breathing.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Flecainide Sandoz

Storage

Keep your tablet in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Flecainide Sandoz in a cool dry place, protected from light, where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Flecainide Sandoz past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Flecainide Sandoz is available in blister packs of 60 tablets.

The 50 mg tablets are round, white, and marked with "C" on one side and "FI" on the other side.

The 100 mg tablets are round, white, and scored on both sides. One side is marked with "C" above the score-line and "FJ" below the score-line. The 100 mg tablets can be divided into equal halves.

Ingredients

Active ingredient:

- flecainide acetate.

Inactive ingredients:

- croscarmellose sodium
- magnesium stearate
- pregelatinised maize starch
- maize starch
- microcrystalline cellulose.

Flecainide Sandoz does not contain lactose, sucrose, tartrazine or any other azo dyes.

Sponsor details

Boucher & Muir Pty Ltd
Level 9, 76 Berry Street
North Sydney NSW 2060

Supplier:

Sandoz Pty Limited
54 Waterloo Road
Macquarie Park
NSW 2113
Australia

Flecainide Sandoz 50 mg tablets: AUST R 232473

Flecainide Sandoz 100 mg tablets: AUST R 232474

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