

# Flecainide Sandoz

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Flecainide Sandoz?

Flecainide Sandoz contains the active ingredient flecainide acetate. Flecainide Sandoz is used to treat a heart condition called arrhythmia, which is an irregular or abnormal heartbeat.

For more information, see Section [1. Why am I using Flecainide Sandoz?](#) in the full CMI.

### 2. What should I know before I use Flecainide Sandoz?

Do not use if you have ever had an allergic reaction to Flecainide Sandoz or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Flecainide Sandoz?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Flecainide Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Flecainide Sandoz?

- The usual starting dose of Flecainide Sandoz is 50 to 100 mg every 12 hours. The usual maximum dose is 300 mg per day, however some patients may need up to 400 mg per day. Follow your doctor's instructions exactly.
- The dose for Flecainide Sandoz is usually around 2 mg/kg body weight and is given in a hospital. Your doctor may vary the dose to suit your condition.

More instructions can be found in Section [4. How do I use Flecainide Sandoz?](#) in the full CMI.

### 5. What should I know while using Flecainide Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• If you are about to start on any new medicines, remind your doctor and pharmacist that you are taking Flecainide Sandoz.</li><li>• If you are going to have surgery, tell the surgeon and anaesthetist that you are taking Flecainide Sandoz.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Follow your doctor's instructions exactly. Do not stop taking Flecainide Sandoz or lower the dose without first checking with your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Flecainide Sandoz affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Flecainide Sandoz in a cool dry place, protected from light, where the temperature stays below 25°C.</li><li>• Keep out of reach of children</li><li>• Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it in the bathroom or near a sink, or in the car or on window sills.</li></ul>

For more information, see Section [5. What should I know while using Flecainide Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include minor and temporary dizziness, blurred eyesight, double vision and not able to stand bright lights, nausea, difficulty breathing, tiredness, headache and chest pain.

Serious side effects include irregular or rapid heartbeat and dizziness. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Flecainide Sandoz \*

**Active ingredient(s):** *Flecainide acetate* (fleck-ain-ide-ass-e-tate)

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Flecainide Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Flecainide Sandoz.**

**Where to find information in this leaflet:**

- [1. Why am I using Flecainide Sandoz ?](#)
- [2. What should I know before I use Flecainide Sandoz ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Flecainide Sandoz ?](#)
- [5. What should I know while using Flecainide Sandoz ?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Flecainide Sandoz?

**Flecainide Sandoz contains the active ingredient flecainide acetate.** Flecainide Sandoz is 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.

### 2. What should I know before I use Flecainide Sandoz?

#### Warnings

**Do not use Flecainide Sandoz if:**

- 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.

**Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes 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.
- have a pacemaker fitted.

Your doctor may prescribe a lower dose for you.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.**

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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 may interfere with Flecainide Sandoz and affect how it works.**

- 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 (lignocaine)]
- certain medicines used to treat epilepsy [e.g. phenytoin, phenobarbital (phenobarbitone) and carbamazepine]
- cimetidine, used to treat stomach ulcers

### **Medicines that may increase the effect of Flecainide Sandoz include:**

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Flecainide Sandoz.**

## **4. How do I use Flecainide Sandoz?**

### **How much to take / use**

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 / use Flecainide Sandoz**

- 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 Flecainide Sandoz**

- 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 use Flecainide Sandoz**

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

**Do not take a double dose to make up for the dose you missed.**

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.

### **If you use too much Flecainide Sandoz**

If you think that you have used too much Flecainide Sandoz, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using Flecainide Sandoz?**

### **Things you should do**

**If you are about to start on any new medicines, remind your doctor and pharmacist that you are taking Flecainide Sandoz.**

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Flecainide Sandoz. It may affect other medicines used during surgery.**

### **Call your doctor straight away 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.
- become pregnant while taking this medicine, tell your doctor immediately.
- 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.**

Remind any doctor, dentist or pharmacist you visit that you are using Flecainide Sandoz.

### Things you should 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.**

### Driving or using machines

**Tambocor can cause dizziness light headedness, faintness and problems with your vision, therefore**

Do not drive or use any machines or tools.

### Looking after your medicine

- Store below 25°C.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Heat and damp can destroy some medicines.

**Keep it where young children cannot reach it.**

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

### Disposal

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines. **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• dizziness or light-headedness</li> <li>• vision problems, e.g. double vision, blurred vision, difficulty focusing, light sensitivity</li> <li>• nausea or vomiting, loss of appetite</li> <li>• fatigue, tiredness, weakness</li> <li>• increased sweating, flushing, dry mouth</li> <li>• fever, joint or muscle pain</li> <li>• abdominal problems, e.g. constipation, abdominal pain, diarrhea</li> <li>• tremor, nervousness, sleepiness, insomnia (difficulty sleeping)</li> <li>• co-ordination problems and difficulties in movement, e.g. tics</li> <li>• skin problems, e.g. tingling, decreased sensitivity or numbness, rash, itching</li> <li>• coughing</li> <li>• ringing in the ears</li> <li>• urination problems</li> <li>• oedema (build-up of fluid in the tissues).</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• fast or irregular heartbeat, chest pains or fainting.</li> <li>• serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)</li> <li>• severe light-headedness or dizziness</li> <li>• difficulty breathing.</li> </ul>	<p><b>These may be serious side effects. You may need urgent medical attention.</b></p> <p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

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

You may not experience any of them.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

This leaflet was prepared in This leaflet was revised in May 2025.

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Flecainide Sandoz contains

<b>Active ingredient (main ingredient)</b>	flecainide acetate.
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• croscarmellose sodium</li><li>• magnesium stearate</li><li>• pregelatinised maize starch</li><li>• maize starch</li><li>• microcrystalline cellulose.</li></ul>
<b>Potential allergens</b>	None

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

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Flecainide Sandoz looks like

Flecainide Sandoz 50 mg tablets: AUST R 232473

Flecainide Sandoz 100 mg tablets: AUST R 232474

### Who distributes Flecainide Sandoz

#### Sponsor:

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

#### Supplier:

Sandoz Pty Limited  
North Sydney  
NSW 2060  
Australia  
Tel 1800 726 369