

FLECATAB

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 FLECATAB?

FLECATAB contains the active ingredient flecainide acetate. FLECATAB is used to treat a heart condition called arrhythmia. Arrhythmia is an irregular or abnormal heartbeat.

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

2. What should I know before I use FLECATAB?

Do not use if you have ever had an allergic reaction to flecainide acetate 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 FLECATAB?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FLECATAB 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 FLECATAB?

- The usual starting dose is 50 mg to 100 mg every twelve hours.
- The recommended maximum dose is 300 mg a day. However, it may be increased up to 400 mg a day in certain patients.

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

5. What should I know while using FLECATAB?

Things you should do
<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist that you visit that you are taking FLECATAB.• If you are going to have surgery, tell the surgeon

	<p>or anaesthetist that you are taking this medicine.</p> <ul style="list-style-type: none"> ● If you become pregnant while taking FLECATAB, tell your doctor immediately.
Things you should not do	<ul style="list-style-type: none"> ● Follow your doctor's instructions exactly. Do not stop taking FLECATAB or lower the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> ● FLECATAB can cause dizziness, light headedness, faintness and problems with your vision, therefore do not drive or use any machines or tools until you know how FLECATAB affects you.
Looking after your medicine	<ul style="list-style-type: none"> ● Keep your FLECATAB tablets in a cool dry place, protected from light, where the temperature stays below 30°C. ● Keep out of reach of children.

For more information, see Section [5. What should I know while using FLECATAB?](#) 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.

FLECATAB

Active ingredient(s): *flecainide acetate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLECATAB. **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 FLECATAB.**

Where to find information in this leaflet:

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

1. Why am I using FLECATAB?

FLECATAB contains the active ingredient flecainide acetate. FLECATAB belongs to a group of drugs called antiarrhythmic medicines which slow down the impulses that cause the heart to beat in an irregular or abnormal way.

FLECATAB is used to treat a heart condition called arrhythmia. Arrhythmia is an irregular or abnormal heartbeat.

2. What should I know before I use FLECATAB?

Warnings

Do not use FLECATAB if:

- you are allergic to flecainide acetate, or any of the ingredients listed at the end of this leaflet.
Some of the Symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue, or other parts of the body
 - rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

- you have heart, liver, or kidney disease unless your doctor says it is suitable for you
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have used FLECATAB before and had any problems you think may have been caused by it

- have high or low potassium levels in the blood (hyperkalaemia or hypokalaemia).
- have problems with your heart, liver or kidney
- take any medicines for any other condition.

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

Do not take FLECATAB tablets if you are pregnant or intend to become pregnant.

FLECATAB may affect your developing baby if you take it during pregnancy. Talk to your doctor if you are breastfeeding or intend to breastfeed. There is a possibility that the active ingredient in FLECATAB passes into breast milk and may affect your baby.

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.

Some medicines may interfere with FLECATAB and affect how it works.

It is particularly important to tell your doctor if you are taking any of the following:

- medicines used to treat high blood pressure, angina or other heart conditions (including arrhythmias), for example, digoxin, propranolol, atenolol, labetalol, alprenolol, pindolol, metoprolol, timolol, oxprenolol, sotalol, disopyramide, verapamil, amiodarone, diltiazem or nifedipine
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbital
- cimetidine, a medicine commonly used to treat reflux and ulcers
- medicines used to make urine more alkaline (e.g. Ural, Citravescent).

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

4. How do I use FLECATAB?

How much to take

The dose varies from patient to patient.

The usual starting dose is 50 mg to 100 mg every twelve hours. Your doctor may increase this dose depending on how you respond to this medicine.

The recommended maximum dose is 300 mg a day. However, it may be increased up to 400 mg a day in certain patients.

How to take FLECATAB

Swallow the tablets with a glass of water.

FLECATAB can be taken with or without food.

If you forget to use FLECATAB

FLECATAB should be used regularly at the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you miss your dose at the usual time, take the missed dose as soon as you remember.

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.

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

If you use too much FLECATAB

If you think that you have taken too many FLECATAB tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 FLECATAB?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FLECATAB.

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

Call your doctor straight away if you:

- become pregnant while taking FLECATAB
- feel your heart condition is becoming worse

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

Things you should not do

- do not stop taking your medicine, or change the dose, without checking with your doctor.
- do not give your medicine to anyone else, even if they have the same condition as you.

- do not take FLECATAB to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FLECATAB affects you.

FLECATAB may cause dizziness, lightheadedness, faintness or blurred vision in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

- store below 30°C
- protect from light

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Keep it where young children cannot reach it.

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">• Minor, temporary dizziness• blurred vision, double vision, eyes more sensitive to light• nausea• difficulty in breathing• tiredness• headache• chest pain	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• irregular or rapid heartbeat• dizziness (do not stop taking FLECATAB but see your doctor or pharmacist)	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.

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.

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. 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.

7. Product details

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

What FLECATAB contains

Active ingredient (main ingredient)	flecainide acetate
Other ingredients (inactive ingredients)	croscarmellose sodium microcrystalline cellulose magnesium stearate
Potential allergens	Sulfites (trace)

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

What FLECATAB looks like

FLECATAB tablets are available in 2 strengths:

- FLECATAB 50 mg are normal convex white tablets debossed "FC" over "50" on one side and "G" on the other. Each blister pack contains 60 tablets (AUST R 344750).
- FLECATAB 100 mg are normal convex white tablet, debossed "FC/100" on one side and "G" on the other. Each blister pack contains 60 tablets (AUST R 68651).

Who distributes FLECATAB

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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