

FLECATAB

flecainide acetate

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about FLECATAB.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking FLECATAB against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What FLECATAB is used for

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

FLECATAB belongs to a group of medicines called antiarrhythmic agents. These medicines help the heart beat regularly.

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

Your doctor may have prescribed FLECATAB for another reason.

FLECATAB is available only with a doctor's prescription.

FLECATAB is not recommended for use in children.

The safe use and effectiveness of FLECATAB in treating these

disorders, for this age group, has not been established.

There is no evidence that FLECATAB is addictive.

Before you take FLECATAB

When you must not take it

Do not take FLECATAB if you have an allergy to:

- any medicine containing flecainide acetate (e.g. Tambocor)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or troubled breathing.

Do not take FLECATAB if you have certain other severe heart conditions, liver or kidney disease unless your doctor says it is suitable for you.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- any other heart conditions, including if you have ever had a heart attack
- kidney problems
- liver problems
- high or low potassium levels in the blood (hyperkalaemia or hypokalaemia).

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking FLECATAB during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking FLECATAB during breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking FLECATAB.

Taking other medicines

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

Some medicines and FLECATAB, or may interfere with each other. These include:

- 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

- some 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).

These medicines may be affected by FLECATAB or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take FLECATAB

Follow all directions given to you by your doctor and pharmacist carefully.

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.

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 it

Swallow the tablets with a glass of water.

When to take it

FLECATAB can be taken with or without food.

Take your medicine at about 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.

How long to take it

To properly control your condition, FLECATAB must be taken every day.

Continue taking FLECATAB for as long as your doctor recommends.

If you forget to take it

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much FLECATAB. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking FLECATAB

Things you must do

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

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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.

If you feel your heart condition is becoming worse, tell your doctor immediately.

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

Things you must not do

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

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

Do not stop taking your medicine, or change the dose, without checking with your doctor.

Stopping FLECATAB or changing the dose suddenly may make your condition worse.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

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

This medicine helps most people with arrhythmia, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you notice any of the following:

- irregular or rapid heartbeat
- dizziness, usually this is a minor and a temporary effect which goes away. If dizziness is severe, do not stop taking FLECATAB but see your doctor or pharmacist
- headache, chest pain
- tiredness
- blurred vision, double vision, eyes more sensitive to light
- nausea
- difficulty in breathing

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

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

After using FLECATAB

Storage

Keep your tablets 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 your tablets in a cool dry place where the temperature stays below 30°C. Protect from light.

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

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FLECATAB tablets are available in 2 strengths:

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

Ingredients

The active ingredient in FLECATAB is flecainide acetate.

- Each FLECATAB 50 mg tablet contains 50 mg of flecainide acetate.
- Each FLECATAB 100 mg tablet contains 100 mg of flecainide acetate.

The tablets also contain:

- croscarmellose sodium
- microcrystalline cellulose
- magnesium stearate.

FLECATAB tablets contain trace amount of sulfites.

Supplier

FLECATAB is supplied in Australia by:

Alphapharm Pty Limited trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration number:

FLECATAB 50 mg: AUST R 344750

FLECATAB 100 mg: AUST R 68651

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