

Flecatab

contains the active ingredient 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 are allergic to:

- * medicines containing flecainide acetate (eg. 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 heart conditions.

Your doctor will tell you whether you can take Flecatab.

Do not take Flecatab if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Flecatab if the packaging shows signs of tampering or the tablets do not look quite right.

Talk to your doctor if you are not sure whether you should start taking this medicine.

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 may be affected by Flecatab, or may affect how well it works. These include:

- * other medicines used to treat arrhythmias
- * medicines used to treat high blood pressure
- * medicines used to treat angina or other heart conditions
- * some medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone
- * cimetidine, a medicine commonly used to treat reflux and ulcers
- * medicines used to make urine more alkaline (eg. Ural, Citravescent).

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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.

How to take Flecatab

Swallow the tablets with a glass of water.

When to take Flecatab

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 Flecatab for

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

Keep taking Flecatab for as long as your doctor recommends.

If you forget to take Flecatab

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 Flecatab (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

Before starting any new medicine, tell your doctor and pharmacist that you are taking Flecatab.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Flecatab.

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

If you become pregnant while taking Flecatab, tell your doctor.

Things you must not do

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

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

Do not use Flecatab to treat any other conditions unless your doctor tells you to.

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

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.

Flecatab 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.

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

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

You may not experience any of them.

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

- * dizziness or lightheadedness
- * headache, tiredness or weakness
- * blurred vision, double vision, eyes more sensitive to light
- * feeling sick, stomach pain
- * constipation
- * skin rash.

Tell your doctor as soon as possible if you notice any of the following:

- * fainting
- * passing little or no urine
- * yellowing of the eyes or skin
- * shaking or tremors
- * bleeding or bruising more easily than normal
- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * tiredness with headaches, dizziness, looking pale and being short of breath when exercising.

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

- * pain or tightness in the chest
- * irregular, slow or fast heart beat
- * shortness of breath, often together with chest pain or swelling of the ankles and feet
- * vomiting blood or material that looks like coffee grounds
- * bleeding from your back passage (rectum), black sticky stools or bloody diarrhoea
- * seizures or fits.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using Flecatab

Storage

Keep Flecatab 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.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Flecatab or any other medicine in the bathroom or near a sink.

Do not leave Flecatab in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Flecatab, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Flecatab is a round white tablet marked "FC" over "100" on one side, and "G" on the other. Each pack contains 60 tablets.

Ingredients

The active ingredient in Flecatab is flecainide acetate. Each tablet contains 100 mg of flecainide acetate.

The tablets also contain:

- * croscarmellose sodium
- * cellulose - microcrystalline
- * magnesium stearate.

Flecatab tablets are gluten free.

Supplier

Flecatab is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration number:

AUST R 68651

This leaflet was prepared on 12 April 2005.