

Consumer Medicine Information

Flecainide BNM

Flecainide acetate 50 mg & 100 mg tablets

What is in this leaflet

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

This leaflet answers some common questions about Flecainide BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

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 BNM 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 BNM is used for

Flecainide BNM is used to treat a heart condition called arrhythmia, which is an irregular or abnormal heart beat. The active ingredient, flecainide acetate, belongs to a group of medicines called anti-arrhythmics, which slow down the impulses that cause the heart to beat in an irregular or abnormal way.

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 BNM is only available with a doctor's prescription.

Flecainide BNM is not addictive.

Before you take Flecainide BNM

Flecainide BNM is not suitable for everyone.

When you must not take it

Do not take Flecainide BNM if you are allergic to any medicine containing flecainide or any of the ingredients listed at the end of this leaflet.

Do not take Flecainide BNM if you:

- suffer from certain other heart conditions, different from the heart condition for which you are taking this medicine
- are taking certain other medicines for arrhythmia (irregular or abnormal heart beat)
- have severe liver or kidney disease unless your doctor says it is suitable for you.

Do not take it after the expiry date 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 BNM, 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:

- any arrhythmia after heart surgery
- 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 BNM 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 BNM passes into breast milk and there is a possibility that your baby may be affected. Flecainide BNM 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 BNM to a child aged 12 years and under.

Flecainide BNM is not recommended for use in children under 12 years, unless you and your doctor have discussed the risks and benefits involved.

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

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 health care professional who is prescribing a new medicine for you that you are taking Flecainide BNM.

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

- medicines used to treat high blood pressure, angina or other heart conditions (e.g. digoxin, diuretics, beta blockers such as propranolol, atenolol, labetalol, alprenolol, pindolol, metoprolol, timolol, oxprenolol and sotalol)
- other medicines used to treat irregular or abnormal heart beat (e.g. disopyramide, verapamil, diltiazem, nifedipine, amiodarone, lidocaine and quinidine)
- certain medicines used to treat epilepsy (e.g. phenytoin, phenobarbital and carbamazepine)
- cimetidine, used to treat stomach ulcers
- medicines used to treat depression (e.g. paroxetine, fluoxetine and some other antidepressants)
- astemizole and terfenadine, used to treat allergies
- quinine and halofantrine, used to treat malaria
- medicines used to treat HIV infections (e.g. ritonavir, lopinavir and indinavir)
- terbinafine, used to treat fungal infections
- bupropion, used as an anti-smoking medicine.

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

How to take Flecainide BNM

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 BNM you should take. In adults the usual starting dose of flecainide is 50 to 100 mg every 12 hours. Your doctor may gradually increase this dose. The usual maximum is 300 mg per day, however some patients may need up to 400 mg per day.

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 BNM may not work as well and your problem may not improve.

When to take it

Flecainide BNM is usually taken twice a day.

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

How long to take it

Do not stop taking this medicine unless your doctor tells you to.

It is very important to follow your doctor's instructions exactly. Never change the dose yourself.

If you are unsure whether you should stop taking Flecainide BNM, 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 BNM

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 BNM. 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.

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 BNM to treat any other complaints unless your doctor tells you to.

Do not stop taking Flecainide BNM 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 BNM affects you.

It may cause dizziness or double vision or blurred vision 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, or if anyone else takes your medicine

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest

hospital, if you think that you or anyone else may have taken too much Flecainide BNM.

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 BNM.

Like all medicines, Flecainide BNM 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 or pharmacist if you notice any of the following and they worry you:

- dizziness or light-headedness
- problems with vision, e.g. double-vision, blurred vision, difficulty focusing, light sensitivity
- headache
- nausea or vomiting
- fatigue, tiredness, weakness
- abdominal problems, e.g. constipation, abdominal pain, loss of appetite, diarrhoea, fullness
- skin problems, e.g. tingling, decreased sensitivity or numbness, increased sweating, flushing, rash
- coordination problems and difficulties in movement, e.g. tics
- ringing in the ears and vertigo (spinning sensation)
- tremor
- depression or anxiety
- insomnia (difficulty sleeping)
- fever
- oedema (build-up of fluid in the tissues) and discomfort.

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.

- rash, itching or hives on the skin.

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 BNM

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 Flecainide BNM in a cool dry place 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 BNM 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 BNM is available in blister packs of 60 tablets.

The 50 mg tablets are round, white in colour, embossed with “C” on one side and have the inscription “FI” on the other side.

The 100 mg tablets are round, white in colour, and scored on both sides. One side has the inscription “FJ” on top of the score-line and “C” 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
- starch - pregelatinised maize
- starch - maize
- cellulose - microcrystalline.

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

Sponsor details

BNM Group
39 Anzac Road
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