

Package leaflet: Information for the user

Flecaïnideacetaat ratiopharm 100 mg, tabletten flecainide acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Product name> is and what it is used for
2. What you need to know before you take <Product name>
3. How to take <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

1. What <Product name> is and what it is used for

<Product name> belongs to the group of medicines that work against cardiac arrhythmia (known as anti-arrhythmics). It inhibits stimulus conduction in the heart and extends the time during which the heart is at rest, causing the heart to pump normally again.

<Product name> is used

- for certain serious cardiac arrhythmias, which are often expressed as serious palpitations of the heart or tachycardia.
- for serious cardiac arrhythmias that did not respond well to treatment with other medicines, or when other treatments cannot be tolerated.

2. What you need to know before you take <Product name>

Do not use <Product name>

- if you are allergic to flecainide or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from another heart condition, different from the heart condition for which you are taking this medicine. If you are unsure, or if you would like additional information, consult your doctor or pharmacist,
- if you are taking certain other antiarrhythmics (sodium channel blockers) as well,
- if you suffer from Brugada syndrome (a genetic cardiac disease).

Warnings and precautions

Talk to your doctor or pharmacist before using <Product name>.

- if you suffer from a reduced liver function and/or reduced kidney function, since the concentration of flecainide in the blood may increase. In that event, your doctor may regularly have the concentration of flecainide in the blood checked,

- if you are elderly, since the concentration of flecainide in the blood may increase. This should be taken into consideration when making dose adjustments,
- if you have a permanent pacemaker or temporary pacing electrodes,
- if you have suffered from cardiac arrhythmias after heart surgery,
- if you have a history of congestive heart failure or myocardial dysfunction,
- if you suffer from severe bradycardia or pronounced hypotension. These conditions should be corrected before using <Product name>,
- if you have experienced a heart attack.

Flecainide, like other antiarrhythmics, may cause proarrhythmic effects, i.e. it may cause the appearance of a more severe type of arrhythmia, increase the frequency of an existing arrhythmia or the severity of the symptoms (see section 4. Possible side effects).

Treatment with flecainide should be started under medical supervision (if necessary in the hospital).

Treatment with oral flecainide should be under direct hospital or specialist supervision for patients with:

- Certain rapid cardiac arrhythmias (AV nodal reciprocating tachycardia); Cardiac arrhythmias associated with WPW syndrome (Wolff-Parkinson-White syndrome) and other disorders of conduction pathways.
- Occasionally occurring irregular heartbeat (Paroxysmal fibrillation) with disabling symptoms.

A lowered or elevated level of potassium in the blood may influence the effect of <Product name>. Electrolyte disturbances (e.g. hypo- and hyperkalaemia) should be corrected before using <Product name>.

Diuretics, medicines that stimulate bowel movement (laxatives) and adrenal cortex hormones (corticosteroids) may lower the level of potassium in the blood. In that event, your doctor may have the amount of potassium in your blood checked.

Children and adolescents

<Product name> is not approved for use in children under 12 years of age, however signs of toxicity have been observed during treatment with flecainide in children who reduced their intake of milk and in infants who were switched from milk formula to dextrose feedings.

If your doctor has prescribed flecainide to your child, make sure that your child's intake of dairy products (e. g. milk, instant formula, yoghurt) remains stable during treatment. Consult your doctor before altering your child's intake of dairy products.

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you use certain other medicines along with <Product name>, the medicines can sometimes affect the way each other work and/or their side effects (i.e. there may be interactions).

Interactions may occur when using this medicine with for example:

- sodium channel blockers (class I anti arrhythmics), such as disopyramide and quinidine: see section "Do not use <Product name>“,
- digoxin (a medicine to stimulate the heart); <Product name> may raise the level of digoxin in your blood,
- beta blockers such as propranolol (medicines that reduce the heart's pumping function),

- calcium channel blockers, such as verapamil (lowers the blood pressure),
- phenytoin, phenobarbital and carbamazepine (certain medicines against epilepsy): the breakdown of flecainide may be accelerated by these substances;
- cimetidine (an antacid); this may increase the effect of <Product name>,
- amiodarone (for heart conditions); the dose of flecainide must be reduced for some patients,
- paroxetine, fluoxetine and certain other antidepressants named “tricyclic antidepressants” (medicines against depression),
- clozapine, haloperidol and risperidone (medicines used to treat schizophrenia, also called neuroleptics),
- mizolastine, astemizole and terfenadine (medicines against allergies),
- quinine and halofantrine (medicines against malaria),
- ritonavir, lopinavir and indinavir (medicines to treat HIV-infections),
- diuretics, laxatives (medicines that stimulate bowel movement) and adrenal cortex hormones (corticosteroids): your doctor may have the amount of potassium in your blood checked,
- terbinafine (to treat fungal infections),
- bupropion (anti-smoking drug).

<Product name> with food and drink

<Product name> should be taken on an empty stomach or at least one hour before a meal.

Dairy products (milk, infant formula, and possibly yoghurt) may reduce the absorption of flecainide in infants and children. <Product name> is not approved for use in children under 12 years of age, however signs of toxicity have been observed during treatment with flecainide in children who reduced their intake of milk and in infants who were switched from milk formula to dextrose feedings.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During pregnancy <Product name> should only be used if the benefit outweighs the risks since flecainide has been shown to cross the placenta in patients taking flecainide during pregnancy. If <Product name> is used during pregnancy maternal flecainide plasma levels should be monitored. You must consult your doctor as soon as you suspect you are pregnant, or if you want to have children.

Flecainide is secreted in the mother's milk. <Product name> should only be used during breast-feeding if the benefit outweighs the risks.

Driving and using machines

If you suffer from side effects such as dizziness, double vision or blurred vision, or if you feel light in the head, then your ability to react may have been reduced. This may be dangerous in situations that demand concentration and attentiveness, such as using the road, handling dangerous machinery or working at heights. If you are unsure whether <Product name> is having a negative effect on your ability to drive, discuss this with your doctor.

<Product name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take <Product name>

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Posology

Your doctor will prescribe a personalised dose, adjusted to fit your complaints. Treatment with flecainide will normally be started under medical supervision (if necessary, in the hospital). Follow your doctor's advice closely when taking flecainide. Check with your doctor or pharmacist if you are not sure.

When and how should the tablets be taken?

Take the tablets by swallowing them with sufficient fluid (e.g. water). The daily dose is usually taken split up over the day, on an empty stomach, or at least one hour before meals.

The general dose is just a guideline and is as follows:

the usual starting dose lies between 100 and 200 mg. The dose may be increased by your doctor to a maximum of 400 mg a day.

More elderly patients

Your doctor may prescribe a lower dose for you. The dose for elderly patients should not exceed 300 mg daily (or 150 mg twice daily).

Children

These tablets should not be taken by children under the age of 12 years.

Patients with a reduced kidney or liver function

Your doctor may prescribe a lower dose for you.

Patients with a permanent pacemaker

The daily dose must not exceed 100 mg twice a day.

Patients who are simultaneously being treated with cimetidine (medicine against gastric disorders) or amiodarone (medicine against cardiac arrhythmia)

The doctor will check you regularly, and a lower dose will be prescribed for some patients.

During treatment, your doctor will regularly determine the level of flecainide in the blood and what is known as an electrocardiogram (ECG) of the heart will be taken. A simple ECG must be taken once a month and a more extensive ECG once every three months. An ECG will be taken every 2 to 4 days at the start of the treatment and when the dose is raised.

An ECG must be taken more frequently for patients who are receiving a smaller dose than is usually prescribed. The doctor can adjust the doses at intervals of 6 to 8 days. An ECG will be taken for these patients at weeks 2 and 3 after the start of the treatment.

If you take more <Product name> than you should

If you suspect an overdose, you must alert a doctor immediately.

If you forget to take <Product name>

Take the dose when you discover that you have forgotten to take it, unless you only discover this when it is almost time to take your next dose. In the latter case, you must not take the dose that you forgot as an addition but should continue to follow your schedule. It is important to take the tablets according to the schedule. Consult your doctor if you have any doubts.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking <Product name>

If you suddenly stop taking <Product name> you will not get withdrawal symptoms. However, the cardiac arrhythmia will no longer be being controlled as intended. So never stop using it without your doctor knowing.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like other anti-arrhythmics flecainide can have the effect of inducing arrhythmia. The existing arrhythmia may worsen or a new arrhythmia may occur. The risk of pro-arrhythmic effects is most likely in patients with a structural heart disease and / or significant impairment of the heart function.

Concerning the heart, the most commonly occurring side effects are decrease or increase of the heart rate (bradycardia, tachycardia), palpitations, cardiac arrest, cardiac failure, chest pain, heart attack and lowering of blood pressure (hypotension).

The most commonly reported side effects are giddiness and visual disturbances, which occur in approximately 15% of patients. These side effects usually disappear after a few days if the therapy is continued or can be eliminated by reducing the dose.

Other side effects that may occur include the following:

very common (may affect more than 1 in 10 people):

dizziness, light-headedness, problems with vision, such as double vision, blurred vision and difficulties to focus

common (may affect up to 1 in 10 people):

appearance of a more severe type of arrhythmia or an increase in frequency or severity of an existing arrhythmia (proarrhythmia), shortness of breath, weakness, tiredness (fatigue), fever, built up of fluid in the tissue (oedema) and discomfort

uncommon (may affect up to 1 in 100 people):

nausea, vomiting, constipation, abdominal pain, anorexia, diarrhoea, dyspepsia (pain in upper abdomen, fullness), flatulence, decrease in red and white blood cells and platelets, increased heart rate in patients with atrial flutter, allergic skin reactions such as rash, hair loss, dry mouth, taste disturbances, joint pain (arthralgia) and muscle pain (myalgia) possibly with fever

rare (may affect up to 1 in 1,000 people):

lung inflammation (pneumonia), tingling of the skin (“as if ants are walking over it”), coordination problems, difficulties in movement (tics), decrease of sensitivity, increased sweating, temporary loss of consciousness, ringing in the ears, tremor, spinning sensation (vertigo), flushing, sleepiness, severe depression, anxiety, insomnia, headache, nervous disorders e.g. in the arms and legs, convulsions, confusion, seeing things that are not there (hallucinations), amnesia, hives, elevated liver enzymes with or without jaundice

very rare (may affect up to 1 in 10,000 people):

elevated levels of certain antibodies, corneal deposits, sensitivity of the skin to light

not known (frequency cannot be estimated from the available data):

certain changes in the electrocardiogram (increase in PR and QRS intervals), increase in pacing threshold in patients with pacemakers or temporary pacing electrodes, impairment of the conduction between the atria and ventricles of the heart (second or third degree atrioventricular block), stopped heart beat, slower or faster heart beat, loss of the heart's ability to pump enough blood to the body's tissues, chest pain, low blood pressure, heart attack, feeling your heart beat, a pause in the normal cardiac rhythm (sinus arrest), appearance of a certain pre-existing heart disease (Brugada syndrome) which was not seen before the treatment with <productname>, lung diseases (pulmonary fibrosis and interstitial lung disease), hepatic dysfunction

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the package after EXP. The expiry date refers to the last day of that month. Consult your pharmacist about the shelf life if you have any doubts.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What <Product name> contains**

- The active substance is flecainide acetate.
- Each tablet contains 100 mg flecainide acetate.
- The other ingredients are croscarmellose sodium (E468), magnesium stearate (E470b), pre-gelatinised maize starch, maize starch and microcrystalline cellulose (E460).

What <Product name> looks like and contents of the pack

The tablet is round and white with a break line on one side, with the inscription "FJ" on one side of the line and "C" on the other side, and a break line on the other side. The tablet can be divided into equal halves.

Pack sizes:

Blister: 20, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168 and 180 tablets.

Bottle: 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Ratiopharm GmbH
Graf-Arco-Str.3
89079 Ulm
Duitsland

Fabrikant
Merckle GmbH
Ludwig-Merckle-strasse 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 34516

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Duitsland Flecainid-ratiopharm 100 mg Tabletten
Nederland Flecaïnideacetaat ratiopharm 100 mg, tabletten

Deze bijsluiter is voor het laatst goedgekeurd in mei 2024.

<Detailed information on this medicine is available on the web site of {MA/Agency}>