Package leaflet:
Information for the user

Flecainide Acetate 50 mg tablets
Flecainide Acetate 100 mg tablets

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 Flecainide Acetate is and what it is used for
2. What you need to know before you take Flecainide Acetate
3. How to take Flecainide Acetate
4. Possible side effects
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1. What Flecainide Acetate is and what it is used for

Flecainide 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.

Flecainide Acetate 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 Flecainide Acetate

Do not take Flecainide Acetate
- 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.
- you are taking certain other antiarrhythmics (sodium channel blockers) as well;
- If you know that you have a genetic disease [Brugada syndrome] characterized by abnormal electrocardiogram (ECG)

Warnings and precautions
- Talk to your doctor or pharmacist before taking Flecainide Acetate.
- 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 have a permanent pacemaker or temporary pacing electrodes,
- if you have suffered from cardiac arrhythmias after heart surgery.
- If you have experienced a heart attack.
- if you suffer from severe bradycardia or pronounced hypotension. These conditions should be corrected before using Flecainide Acetate,

The rate of flecainide elimination from plasma may be reduced in the elderly. This should be taken into consideration when making dose adjustments.

Treatment with oral flecainide should be under direct hospital or specialist supervision for patients with:
- Certain rapid cardiac arrhythmias (AV reciprocation 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.

Treatment for patients with other indications should continue to be initiated in hospital.

A lowered or elevated level of potassium in the blood may influence the effect of flecainide.

Electrolyte disturbances (e.g. hypo- and hyperkalaemia) should be corrected before using flecainide.

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
Flecainide Acetate tablets are not recommended for use in children under 12 years of age, however flecainide toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings

Other medicines and Flecainide Acetate

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 flecainide, the medicines can sometimes affect the way each other work and/or their side effects (i.e. there may be interactions).

There may be life threatening or even fatal side effects caused by increased concentration of the drug in the blood due to interactions (see section 4 “Possible side effects”)

Consult a doctor or go to a hospital casualty department straight away.

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 Flecainide Acetate “,
- beta blockers such as propranolol (medicines that reduce the heart’s pumping function),
- amiodarone (for heart conditions); the dose of Flecainide Acetate must be reduced for some patients,
- calcium channel blockers, such as verapamil (lower the blood pressure),
- diuretics, laxatives (medicines that stimulate bowel movement) and adrenal cortex hormones (corticosteroids): your doctor may have the amount of potassium in your blood checked.
- astemizole, mizolastine and terfenadine (medicines against allergies),
- ritonavir, lopinavar and indinavir (medicines to treat HIV-infections),
- fluoxetine, paroxetine, reboxetine and certain other antidepressants named “tricyclic antidepressants”,
- phenytoin, phenobarbital and carbamazepine (medicines against epilepsy): the breakdown of flecainide may be accelerated by these substances,
- clozapine, haloperidol and risperidol (to treat psychotic disorders),
- quinine, quinidine and halofantrine (medicine against malaria),
- terbinafine (to treat fungal infections),
- cimetidine (an antacid); this may increase the effect of Flecainide Acetate,
- bupropion (anti-smoking medicine),
- digoxin (a medicine to stimulate the heart); Flecainide Acetate may raise the level of digoxin in your blood

Flecainide Acetate with food and drink
Dairy products (milk, infant formula and possibly yoghurt) may reduce the absorption of flecainide in children and infants. Flecainide is not approved for use in children below the age of 12 years, however flecainide toxicity has been reported during treatment with flecainide in children who reduced their intake of milk, and in infants who were switched from milk formula to dextrose feedings

Flecainide should be taken on an empty stomach or at least one hour before a meal.

If Flecainide and activated charcoal (e.g. charcoal tablets) are given at the same time, this should only be done after consultation with the doctor, since the absorption of Flecainide from the intestine into the bloodstream and thus the effectiveness of Flecainide is affected.

Pregnancy, breast-feeding and fertility
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 flecainide should not be used unless clearly necessary since flecainide has been shown to cross the placenta in patients taking flecainide during pregnancy. If flecainide 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 mothers milk. Nursing mothers should not breast-feed whilst taking flecainide
Ask your doctor or your pharmacist for advice before taking medicines.

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 be 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 flecainide is having a negative effect on your ability to drive, discuss this with your doctor.

Flecainide 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 Flecainide Acetate

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. You should check with your doctor or pharmacist if you are unsure.

<u>When and how should the tablets be taken?</u>
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 recommended starting dose lies between 50 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 300mg daily (or 150mg twice daily).

Use in 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 100mg 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

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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.

Switch over from IV administration to tablets
Due to the near complete oral bioavailability of flecainide, switching from IV flecainide application to oral flecainide administration is possible without a new dose adjustment. As a rule, an interval of 8 to 12 hours should elapse between the completion of IV administration and the ingestion of the first tablet. Because flecainide has a narrow therapeutic spectrum, close follow up monitoring is required.

If you take more Flecainide Acetate than you should
If you take more flecainide than you should, tell a doctor or go to a hospital casualty department straight away.

If you forget to take Flecainide Acetate
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 Flecainide Acetate
If you suddenly stop taking flecainide 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 arrhythmia drugs, flecainide can have the side effect of causing a heart rhythm disorder. The existing cardiac arrhythmia may worsen or a new cardiac arrhythmia may develop. The risk of these effects is greatest in patients with structural heart disease and/or a significant reduction in cardiac function.

Regarding the heart, the most common side effects are a decrease or increase in heart rate (bradycardia, tachycardia), palpitations, cardiac arrest, heart failure, chest pain, heart attack and decreased blood pressure (hypotension).

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

Very common (may affect more than 1 in 10 people)
- dizziness, vertigo and light-headedness
- visual disturbances, such as double vision, blurred vision and difficulty focusing

Common (may affect up to 1 in 10 people):
- more frequent occurrence of pre-existing arrhythmia (irregular heartbeat)
- shortness of breath
- weakness
- fatigue
- fever
- fluid in the tissues (edema)
- discomfort

Uncommon (may affect up to 1 in 100 people):
- decrease in red and white blood cells and platelets
- libido decreased
- depersonalisation/derealisation disorder
- euphoric mood
- increased dream activity
- apathy
- stupor
- erectile dysfunction
- eye irritation
- photophobia
- rapid involuntary movements of the eyes (nystagmus)
- hypertension
- bronchospasm
- irregular heart beat with increased heartbeat
- nausea
- vomiting
- constipation
- abdominal pain
- decreased appetite
- diarrhea
- flatulence
- dry mouth
- taste disturbances
- dermatitis exfoliative
- pain in upper abdomen, fullness (dyspepsia)
- allergic skin reactions such as rashes, hives and baldness
- production of abnormally large volumes of urine (polyuria)
- urinary retention
- swollen lips, tongue and mouth

Rare (may affect up to 1 in 1000 people):
- seeing things that are not there (hallucinations)
- depression
- confusion
- anxiety
- memory loss (amnesia)
- insomnia
- tingling or numbness
- difficulty in controlling movements (ataxia)
- decrease of sensitivity
- increased sweating (hyperhidrosis)
- fainting (syncope)
- tremor
- flushing
- sleepiness
- headache
- nervous disorders e.g. in the arms and legs
- convulsions
- movement disorder (dyskinesia)
- ringing in the ears
- paresis
- speech disorder
- spinning sensation (vertigo)
- lung inflammation (pneumonia)
- elevated liver enzymes reversible on stopping treatment
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice)
- hives (urticaria)

Very rare (may affect up to 1 in 10,000 people):
- elevated levels of certain antibodies
- small cloudy spots on the eyeball
- sensitivity to sunlight

Not known (frequency cannot be estimated from the available data)
Changes in electrocardiogram (ECG)
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 flecainide, scarring of the lungs or lung disease (named interstitial lung disease which causes breathlessness), liver disorder, anorexia, joint pain and muscle pain.

Although no causal relationship has been established, periodic monitoring of liver function tests should be carried out during flecainide therapy. In patients who develop unexplained jaundice or signs of hepatic dysfunction, it is advisable to discontinue flecainide in order to eliminate the drug as the possible causative agent.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse . This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flecainide Acetate

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine 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 Flecainide Acetate contains
- The active substance is flecainide acetate. Each tablet contains 50 mg or 100 mg of flecainide acetate.
- The other ingredients are cellulose, microcrystalline, croscarmellose sodium, pregelatinized starch, hydrogenated vegetable oil, magnesium stearate.

What Flecainide Acetate looks like and contents of the pack
Tablets

Flecainide Acetate 50mg tablets:
White to off-white, round, biconvex tablets embossed with 'CC' on one side and '11' on the other side.

Flecainide Acetate 100mg tablets:
White to off-white, round, biconvex, scored tablets debossed with '1' and '2' separated by deep score line on one side and 'CC' on the other side. The tablet can be divided into equal doses.

Flecainide Acetate tablets are available in Clear PVC/PVdC - Aluminium foil blister pack and HDPE bottle pack with polypropylene closure.

Blister: 20, 28, 30, 40, 50, 56, 60, 84, 90 and 100 tablets
HDPE: 20,500 and 1000 tablets.

Not all pack sizes may be marketed.

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