PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Flecainide acetate 50mg and 100mg Tablets

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

1. What Flecainide is and what it is used for

Flecainide belongs to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by correcting irregular heartbeats to a normal rhythm.

Flecainide is used to treat:

- an irregularity in the heartbeat (arrhythmia)
- fast heartbeat (tachycardia)
- rapid contractions of heart muscles (atrial fibrillation)

2. What you need to know before you take Flecainide

Do not take Flecainide:

- if you are allergic to flecainide acetate or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from heart failure or some types of heart rhythm disorders
- if you suffer from heart valve disease
- if you have a history of heart attacks
- if you have low blood pressure or a slow beating heart
- if you have a serious heart condition called cardiogenic shock which causes rapid breathing, weakness, looking pale, confusion and can lead to a loss of consciousness
- if you have a heart condition called Brugada Syndrome, which causes you to have a potentially life-threatening heart rhythm disorder
- if you are already taking disopyramide to regulate your heartbeat.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Flecainide:

- if you know you have high or low levels of salt (such as potassium) in your blood
- if you suffer from liver or kidney problems
- if you have a heart rhythm disorder called ‘sick sinus syndrome’
- if you have a pacemaker
- if you suffer from an enlarged heart, or some types of heart disease.

Other medicines and Flecainide

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

- diuretics (water tablets) e.g. furosemide
- corticosteroids for inflammatory conditions such as arthritis e.g. prednisolone
- laxatives to treat constipation
- other medicines used to regulate your heartbeat e.g. digoxin, quinidine, beta-blockers (e.g. atenolol, propranolol), amiodarone, verapamil
- anticonvulsants (for epilepsy) e.g. phenytoin, phenobarbital, carbamazepine
- cimetidine (to treat stomach ulcers)
- antivirals (to treat HIV) e.g. ritonavir, fixed-combination products containing ritonavir
- anti-malarials e.g. quinine
- antihistamines (to treat allergies) e.g. mizolastine, terfenadine
- antidepressants e.g. fluoxetine, paroxetine, reboxetine and tricyclic antidepressants such as imipramine
- bupropion (used as an antidepressant and an anti-smoking aid)
- antifungals e.g. terbinafine
- antipsychotics (to treat mental illness) e.g. clozapine

Flecainide with food and drink

Dairy products like milk, infant formula and possibly yoghurt have been shown to reduce the absorption of flecainide acetate in children and infants. It is not known if this may apply to adults. Talk to your doctor or pharmacist for advice.

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.

Flecainide **should not** be given to pregnant or breast-feeding mothers unless the benefits to the mother outweigh the risks to the baby. If your doctor does decide to give you flecainide, you will be monitored closely during your pregnancy.

Driving and using machines

Do not drive or operate machinery if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine..

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

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

- Flecainide tablets should be taken orally.
- The 100mg tablet can be divided into equal doses.

Adults

Your doctor will choose the dose which best suits your condition.

<u>Supraventricular arrhythmias (irregular heartbeat that starts in the upper chambers of your heart)</u>

- The usual dose is either one 50mg tablet or half a 100mg tablet twice daily.
- If necessary, your doctor may increase this dose to a maximum dose of 300mg daily (3 x 100mg tablets or 6 x 50mg tablets).

Ventricular arrhythmias (irregular heartbeat that starts in the lower chambers of your heart)

- The usual dose is either two 50mg tablets or one 100mg tablet twice daily.
- If necessary, your doctor may increase this dose to a maximum dose of 400mg daily (4 x 100mg tablets or 8 x 50mg tablets).

When your condition has been brought under control your doctor may reduce your dose to the lowest dose you need.

Your doctor may wish to start flecainide treatment in hospital where they will perform regular ECGs (electrical tracing of the heart) and monitor your blood flecainide levels. Your doctor may also wish to perform these tests if or when they alter the dose of flecainide you are taking or if you have switched from a different formulation (e.g. from an injection of flecainide).

Patients with liver or kidney problems
Your doctor may give you a lower dose and will closely monitor you.

Patients with a pacemaker
If you have a pacemaker your dose should not exceed 100 mg twice daily. Your doctor will closely monitor you.

Elderly
If you are elderly, your doctor may prescribe a lower starting dose for you.

Children
Flecainide is not recommended for use in children under 12 years of age.

If you take more Flecainide than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take Flecainide
Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Flecainide
Do not stop taking Flecainide tablets without first talking to your doctor. If you suddenly stop taking flecainide you may experience side effects.

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.

If you experience any of the following serious side effects, stop taking Flecainide tablets and seek medical advice immediately:

Common side effects (may affect up to 1 in 10 people):

- fast or irregular heartbeat

Rare side effects (may affect up to 1 in 1,000 people):

- inflammation of the lungs which can cause weakness, breathlessness, cough and raised temperature (pneumonitis)

- changes in liver function with or without yellowing of the skin or whites of the eyes (jaundice), usually reversible on stopping treatment
- fits (convulsions)

Very rare side effects (may affect up to 1 in 10,000 people):
- worsening of eyesight

Not known (frequency cannot be estimated from the available data):
- heart block which can cause lightheadedness, fainting and irregular heart rhythm
- slower heart rhythm, dangerously fast heart rhythm
- heart attack
- a heart disorder called sinus arrest
- chest pain
- scarring of the lungs or lung disease which causes shortness of breath
- heart failure which can cause shortness of breath and swelling of the feet or legs due to fluid retention

Other side effects

Very common side effects (may affect more than 1 in 10 people):
- feeling giddy, dizzy or lightheaded
- blurred or double vision

Common side effects (may affect up to 1 in 10 people):
- breathlessness, difficulty breathing
- weakness
- tiredness
- fever
- excessive fluid in the body (swelling)

Uncommon side effects (may affect up to 1 in 100 people):
- reduction in red blood cell count, which may make the skin pale and cause weakness or breathlessness
- reduction in white blood cell count, which makes you prone to infections
- reduction in platelet count, which can make you bleed or bruise more easily than normal)
- feeling or being sick
- constipation
- stomach pain or discomfort
- reduced appetite
- diarrhoea
- indigestion
- wind (flatulence)
- inflammation of the skin due to allergies, including rash
- hair loss

Rare side effects (may affect up to 1 in 1,000 people):
- depression
- confusion or anxiety
- loss of memory
- difficulty sleeping or sleepiness
- seeing, hearing or feeling things that are not there (hallucinations)

- nervousness
- numbness or weakness of the arms and legs
- tingling, pins and needles
- sudden uncontrollable or abnormal body movements, shaking
- decreased feeling or sensitivity, especially in the skin
- increased sweating
- fainting
- redness of the skin (flushing)
- headache
- ringing in the ears
- a nettle-like rash, hives

Very rare side effects (may affect up to 1 in 10,000 people):
- dry mouth or taste changes
- sensitivity of the skin to sunlight
- painful, swollen joints or muscle pain
- impotence
- raised levels of certain antibodies, which may cause inflammation

Not known (frequency cannot be estimated from the available data):
- low blood pressure
- palpitations
- liver disease

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Flecainide

- 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/blister after EXP. The expiry date refers to the last day of that month.
- 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 contains

- Each tablet contains 50 mg or 100 mg of flecainide acetate..
- **The other ingredients are**: microcrystalline cellulose (pH 101 and pH 102), croscarmellose sodium and magnesium stearate.

What Flecainide looks like and contents of the pack

Flecainide 50 mg are white to off-white, round, biconvex tablets, approximately 6.5 mm in diameter, debossed with “HP” on one side and “183” on the other side.
The 50 mg tablets are available in blister packs of 20, 30, 50, 60 or 100 tablets.

Flecainide 100 mg are white to off-white, round, curved tablets, approximately 8.5 mm in

diameter, debossed with a snap-type break line separating 'H' and 'P' on one side and convex tablet debossed with '184' on other side.
The 100 mg tablets are available in blister packs of 20, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Tillomed Laboratories Limited
220 Butterfield
Great Marlings
Luton
LU2 8DL
United Kingdom

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