

**PACKAGE LEAFLET**

## **Package leaflet: Information for the patient**

### **Flecainide acetate 50mg and 100mg 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 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 Tablets belong to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart.

Flecainide Tablets are used to treat:

- Arrhythmias (irregular heart beat)
- Tachycardia (heart beat too fast)
- Atrial fibrillation (rapid contractions of muscles in the heart).

It is important for your doctor to treat these conditions quickly and effectively in order to prevent more serious heart problems from developing.

There are two strengths of tablet available, 50 mg and 100 mg.

#### **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 have heart failure
- if you have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
- if you have heart block (your heart misses beats)
- if you have long-standing atrial fibrillation (rapid contractions of muscles in the heart)
- if you have or have ever had any heart problems including problems with the valves in your heart or conduction problems
- if you have sinus node dysfunction (a specific condition where your heart beats abnormally)

- if you have had a myocardial infarction (heart attack)
- if you have Brugada Syndrome, a genetic disease that causes severe disturbances of the rhythm of the heart and may lead to sudden death in apparently healthy individuals.
- if you are pregnant or breast-feeding.

Flecainide Tablets are not recommended for use in children under 12 years of age, however, dairy products such as milk, infant formula and possibly yoghurt, may reduce how much flecainide acetate is absorbed in children and infants. If any of the above applies to you tell your doctor or pharmacist.

**Before you take Flecainide, your doctor may check:**

- your fluid levels are correct
- your liver and kidney functions.

This is to check that Flecainide Tablets are right for you and to help the doctor calculate the dose you need.

**Check with your doctor before taking Flecainide if:**

- you have high blood pressure
- you have angina (chest pains)
- you have heart disease
- you have kidney disease or kidney problems
- you have liver disease or liver problems
- you wear a pacemaker.

**Warnings and Precautions**

**Tell your doctor if you are taking any of the following medicines:**

- any other medicine used to treat heart arrhythmias or heart problems such as cardiac glycosides, beta-blockers, verapamil, propranolol or amiodarone
- Medicines to treat high blood pressure
- antidepressants (medicines used to treat depression), such as tricyclic antidepressants, fluoxetine, paroxetine or reboxetine
- anticonvulsants (medicines used to prevent epileptic fits) such as phenytoin, phenobarbital or carbamazepine
- antipsychotics (medicines to treat mental illness) such as clozapine
- antihistamines (medicines to treat allergic reactions) such as mizolastine or terfenadine
- quinine (medicine to treat malaria)
- medicines to treat HIV such as ritonavir, lopinavir or indinavir
- diuretics (water tablets)
- cimetidine (medicine to treat stomach ulcers)
- bupropion (a medicine to help stop you smoking)
- any other medicine, including medicines obtained without a prescription

These medicines may interfere with your treatment.

**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 Flecainide Tablets.

**Driving and using machines:**

Driving ability, operation of machinery and work without a secure fit may be affected by adverse reactions such as dizziness and visual disturbances (if present).

**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 Flecainide Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

**Important:**

**Your doctor will choose the dose that is right for your condition. Usually, your treatment with Flecainide will be started in hospital. If you have switched from a different formulation (e.g. from an injection of Flecainide) your doctor should do so with caution and monitor you closely.**

**Adults:****Supraventricular arrhythmias (Irregular heart beat that starts in the upper chambers of your heart)**

- Flecainide 50mg tablets: The usual dose is one tablet twice a day.
- Flecainide 100mg tablets: The usual dose is half a tablet twice a day.

Your doctor may prescribe up to a total dose of 300 mg daily (3 x 100 mg tablets or 6 x 50 mg tablets).

**Ventricular arrhythmias (Irregular heart beat that starts in the lower chambers of your heart)**

- Flecainide 50mg tablets: The usual dose is two tablets twice a day.
- Flecainide 100mg tablets: The usual dose is one tablet twice a day.

Your doctor may prescribe up to a total dose of 400 mg daily (4 x 100 mg tablets or 8 x 50 mg tablets)

**The elderly and patients with kidney or heart problems:**

- For elderly patients, and patients with kidney or heart problems, the doctor may tell you to take a lower dose. While you are taking this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

**Children:**

- Flecainide Tablets are not recommended for children under 12 years of age, however, dairy products such as milk, infant formula and possibly yoghurt, may reduce how much flecainide acetate is absorbed in children and infants.

**If you take more Flecainide than you should**

If you accidentally take too much, immediately go to the nearest hospital emergency department.

**If you forget to take Flecainide**

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

### **If you stop taking Flecainide**

Do not stop taking Flecainide tablets without first talking to your doctor.

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.

**Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:**

#### **Common (affects 1 in 100 people):**

- your heartbeat changes; it starts to pound, or it gets faster or slower
- you have chest pain
- you become breathless or have other breathing problems
- you have a fever, become flushed or sweat
- you faint or you feel faint

#### **Rare (affects 1 in 10,000 people):**

- you have ringing in your ears
- your skin and eyes begin to go yellow (jaundice)
- you have fits (convulsions).

#### **Other side effects (frequency unknown):**

- heart attack
- cardiac failure/arrest (loss of breathing, and consciousness and loss of heart function)

**Other side effects include the following, if they get serious, please tell your doctor:**

#### **Very common (affects more than 1 in 10 people):**

- dizziness
- double or blurred vision

#### **Common (affects 1 in 100 people):**

- feeling weak or tired
- lack of energy and strength
- swelling (fluid retention)

#### **Uncommon (affects 1 in 1,000 people):**

- blood disorders (reduced red and white blood cell count and reduced platelet count)
- feeling or being sick
- constipation
- stomach pain or indigestion

- loss of appetite
- diarrhoea
- wind
- feeling bloated
- red, itchy or swollen skin rash
- hair loss

**Rare (affects 1 in 10,000 people):**

- vertigo (feeling like the room is spinning)
- confusion and hallucinations
- depression
- feeling anxious (worried)
- forgetfulness
- difficulty sleeping
- numbness, tingling, tickling, prickling or burning sensation of the skin
- unsteady walking, uncontrolled movements or poor coordination, difficulty speaking
- reduced sense of touch
- excessive sweating and flushed skin
- shaking (tremors)
- a strong desire to sleep or sleep for long periods
- headache

**Very rare (affects less than 1 in 10,000 people):**

- small cloudy spots on the eyeball
- sensitivity of the skin to sunlight

**Other side-effects (frequency unknown):**

- lung disease and scarring of the lungs
- liver disease
- joint and/or muscle pain

**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 [www.mhra.gov.uk/yellowcard](http://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 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 Tablets contains**

- The active substance is flecainide acetate. Each 50 mg tablet contains 50 mg of flecainide acetate. Each 100 mg tablet contains 100 mg 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**

The 50 mg tablets 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 100 mg tablets are white to off white, round, curved tablets, approximately 8.5 mm in diameter, debossed with snap type break line separating 'H' and 'P' on one side and convex tablets debossed with '184' on other side of tablet. The tablet can be divided into equal doses.

The 50 mg tablets are available in blister packs of 20, 30, 50, 60 and 100 tablets.

The 100 mg tablets are available in blister packs of 20, 50, 60 and 100 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

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

### **Manufacturer <sup>1</sup>**

MIAS Pharma Limited  
Suite 2, Stafford House, Strand Road  
Portmarnock, Co. Dublin  
Ireland

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

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<sup>1</sup> Only actual site will be listed on printed leaflet