

## PACKAGE LEAFLET: Information for the user

### FLENIDE

Tablets – 50 mg, 100 mg

(Flecainide acetate)

**Read all of this leaflet carefully before you start taking this medicine.**

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Flenide is and what it is used for
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#### **1. WHAT FLENIDE IS AND WHAT IT IS USED FOR**

Flenide tablets contain the active substance flecainide acetate, which belongs to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart.

#### **Flenide is used to treat:**

- Arrhythmias (irregular heart beat)
- Tachycardia (heart beating 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. BEFORE YOU TAKE FLENIDE**

### **Do not take Flenide tablets if you:**

- are allergic to flecainide acetate or any of the excipients of this medicine;
- have heart failure;
- have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
- have heart block (your heart misses beats);
- have long-standing atrial fibrillation (rapid contractions of muscles in the heart);
- have or have ever had any heart problems, including problems with the valves in your heart or conduction problems;
- have sinus node dysfunction (a specific condition where your heart beats abnormally)
- have had a myocardial infarction (heart attack);
- 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;
- are pregnant or breastfeeding.

If any of the above applies to you tell your doctor or pharmacist.

### **Before you take Flenide tablets your doctor may check:**

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

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

### **Take special care with Flenide**

Ask your doctor or pharmacist before taking Flenide if you:

- have high blood pressure;

- have angina (chest pains);
- have heart disease;
- have kidney disease or kidney problems;
- have liver disease or liver problems;
- wear a pacemaker.

## **Children**

Flenide tablets are not recommended for children under 12 years of age.

## **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription, and in particular, any of the following:

- 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 you stop smoking).

These medicines may interfere with your treatment.

## **Pregnancy and breastfeeding**

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

## **Driving and using machines**

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

### **3. HOW TO TAKE FLENIDE**

Always take Flenide tablets exactly as your doctor or pharmacist 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 Flenide tablets 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):

- Flenide 50 mg tablets: The recommended dose is one tablet twice a day;
- Flenide 100 mg tablets: The recommended 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):

- Flenide 50 mg tablets: The recommended dose is two tablets twice a day;
- Flenide 100 mg tablets: The recommended 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**

Flenide 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 Flenide than you should**

If you take more Flenide than you should, or if the children take it accidentally, immediately go to the nearest hospital casualty department.

### **If you forget to take Flenide**

If you forget taking one dose (or more), take the next dose in its usual time.

Do not take a double dose (or higher) to make up a forgotten dose (doses).

### **If you stop taking Flenide**

Do not stop taking Flenide 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 Flenide tablets can cause side effects, although not everybody gets them.

Some side effects could be serious. If you of the side effects listed below appears to you, seek immediate medical help:

#### **Common (may affect up to 1 in 10 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 (may affect up to 1 in 1,000 people):**

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

**Other side effects (how often they happen is 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 (may affect more than 1 in 10 people):**

- Dizziness;
- Double or blurred vision.

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

- Feeling week or tired;
- Lack of energy and strength;
- Swelling (fluid retention).

**Uncommon (may affect up to 1 in 100 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 (may affect up to 1 in 1,000 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 sleeping for long periods;
- Headache.

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

- Small cloudy spots on the eyeball;
- Sensitivity of the skin to sunlight.

**Other side effects (how often they happen is unknown):**

- Lung disease or scarring of the lungs;
- Liver disease;
- Joint pain and muscle pain.

If any of the side effects gets worse or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE FLENIDE TABLETS**

Keep this medicine out of sight and reach of children!

Do not use the tablets after the expiry date which is stated on the package.

Do not store above 25°C!

Keep in the original package to protect it from light and humidity!

## **6. FURTHER INFORMATION**

### **What Flenide tablets contain**

**The active substance** is flecainide acetate.

Flenide 50 mg tablets:

Each tablet contains 50 mg flecainide acetate.

Flenide 100 mg tablets:

Each tablet contains 100 mg flecainide acetate.

### **The excipients** are:

Pregelatinised starch, Microcrystalline cellulose, Maize starch, Croscarmellose sodium,

Magnesium stearate.

### **Contents of the pack**

Flenide 50 mg: box with 30 tablets.

Flenide 100 mg: box with 30 tablets.

### **Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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**This leaflet was last revised in November 2023.**