Tell your doctor or pharmacist if you are taking, to dextrose feedings in infants who were switched from milk formula in children who reduced their intake of milk, and years of age, however flecainide toxicity has recommended for use in children under 12 years. Your doctor may have the amount of potassium in your blood. In that event, your doctor may prescribe a lower dose for elderly patients. The dose for elderly patients should not exceed 300mg daily (or 150mg twice a day). The dose for elderly patients should be adjusted to fit your complaints. Treatment with flecainide will normally be started under medical supervision (if necessary, in the hospital). Ask your doctor or pharmacist for advice before takingthis medicine. Flecainide should be taken on an empty stomach or at least one hour before a meal. Pregnancy, breastfeeding and fertility If you are pregnant or breast-feeding, please consult your doctor or pharmacist. Nurses should not breast-feed whilst taking falcainide. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Flecainide Acetate is used for Use in children Flecainide Acetate 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. The general dose is just a guideline and is as follows. The dose for elderly patients should not exceed 300mg daily (or 150mg twice a day).
Patients with a reduced kidney or liver function
You should only take Flecainide Acetate if your doctor has advised you to do so.

Patients who are simultaneously being treated with citalopram (medicine against gastric disorders) or amiodarone (medicine against cardiac arrhythmia)
The doctor will check you regularly and if 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 elaborate 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 Flecainide Acetate than you should
If you take too much flecainide you should pull the tablet from your mouth and rinse it out 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 after the start of the treatment.

If you stop taking Flecainide Acetate
This leaflet was last revised in 07/2018.

This medicine should not be taken if you have had a previous episode of heart disease, such as previous heart attacks, heart failure or heart rhythm disorders.

If you feel sick after taking Flecainide Acetate, talk to your doctor or pharmacist. This is more likely to happen during the first days of treatment or after the dose is increased.

If you become pregnant while you are taking Flecainide Acetate or if you think you may be pregnant or if you are breastfeeding, you should stop taking Flecainide Acetate and tell your doctor.

Very rare (may affect up to 1 in 10,000 people)
- elevated levels of certain antibodies
- small cloudy spots on the eyelid
- sensitivity to sunlight
Not known (frequency cannot be estimated from the available data)
Changes in electrocardiogram (ECG) increase in pacing threshold in patients with pacemaker patients. Even pacing electrodes, impairment of the conduction between the atria and ventricles of the heart (second or third degree atrioventricular block), stopped heart beat, atrial 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 (Nationally controlled name), scavenging of the lungs or lung disease (named interstitial lung disease which causes breathlessness), liver disorder

Reporting of side effects
If you have 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 the Yellow Card Scheme. You can report side effects more information on the safety of this medicine.

6. Contents of the pack and other information

What Flecainide Acetate contains
- Flecainide acetate. Each tablet contains 25 mg or 50 mg of flecainide acetate.
- The other ingredients are cellulose, microcrystalline, croscarmellose sodium, pregelatinized starch, hydroxypropyl vegetable oil, magnesium stearate.

What Flecainide Acetate looks like and contents of the pack

Flecainide Acetate 50mg tablets
White to off white, round, biconvex tablets embossed with ‘11’ on one side and ‘1’ on the other side.

Flecainide Acetate 100mg tablets
White to off white, round, biconvex 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 parts. The tablet can be divided into equal parts.

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

Blister: 20, 30, 40, 50, 60, 80, 90 and 100 tablets.

HDPE: 20,50 and 1000 tablets.

Not all presentations may be marketed.

Marketing Authorization Holder
UK: Milpharm Limited
Address: Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

MT: Amtunding Pharma (Malta) Limited
Vat. 14. Level 2, Valletta Waterfront
Floriana FNR 1913 Malta

Manufacturer
APL Swift Services (Malta) Limited
HPF 26, Far Industrial Estate, Hal Far Birzebbuga, BZG 3000 Malta

or
Milpharm Limited
Apothekerstrasse 54, Floriana FRN 1913 Malta

This leaflet was last revised in 07/2018.

What Flecainide Acetate is for
Flecainide Acetate is a medicine 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 and does not require any special storage conditions.