Flecainide Acetate 100 mg tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. Summary of Product Characteristics

Flecainide is secreted in the mothers milk. Avoid breast feeding during treatment with Flecainide.

2. Indications

Flecainide is used for treatment of certain rapid cardiac arrhythmias (AV block type 2, certain forms of atrial flutter (AFib) and atrial fibrillation, paroxysmal atrial fibrillation (PAF)).

3. How to take Flecainide

Flecainide tablets are to be swallowed whole with a large glass of water, preferably on an empty stomach. The tablets are not to be cut or chewed.

4. Possible side effects

There may be mild or moderate side effects which usually do not require stopping the treatment.

5. Interactions

Flecainide may interact with other medicines (see section 4.5). The medicines should be used with caution and in accordance with the recommendations of your doctor or pharmacist.

6. Contents of the pack and other information

You have 100 mg of Flecainide Acetate tablets in your pack. If you are unsure how to take Flecainide, consult your doctor or pharmacist.

7. How to store Flecainide

Store below 25°C. Protect from light. Do not refrigerate or freeze. Do not use this medicine after the expiry date on the container. Keep this leaflet. It has important information for you.

8. What is in this leaflet

This leaflet contains information about Flecainide Acetate tablets as well as important information for you.

9. What to do before you take Flecainide

Tell your doctor and pharmacist what medicine you are taking. Also tell them if you have any other medical conditions.

10. What to do if you already have Flecainide

If you have already taken Flecainide, it is important you talk to your doctor or pharmacist before taking another medicine.

11. What to do if you are pregnant, breast-feeding or planning a pregnancy

If you are pregnant, breast-feeding or planning a pregnancy, ask your doctor or pharmacist for advice before taking this medicine.

12. What to do if you have a genetic disease

If you know that you have a genetic disease, consult your doctor or pharmacist for advice before taking this medicine.

13. Kidney function

Tell your doctor or pharmacist if you have kidney function, since the concentration of Flecainide is increased.

14. Liver function

If you have liver function, talk to your doctor or pharmacist before taking this medicine.

15. Blood levels

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

16. Blood pressure

Tell your doctor or pharmacist if you have problems with blood pressure.

17. Drug interactions

Flecainide may interact with other medicines (see section 4.5). The medicines should be used with caution and in accordance with the recommendations of your doctor or pharmacist.

18. Flecainide Acetate tablets

This medicine contains less than 1 mmol (23 mg) per tablet, that is to say sodium (23 mg) per tablet, that is to say 'sodium-free'.

19. Medical conditions

Tell your doctor or pharmacist if you have any medical conditions.

20. Other ingredients

This medicine contains the following other ingredients (listed in order of decreasing concentration):...
in the blood and what is known as an
electrocardiogram (ECG) of the heart will be
taken. A single ECG may be taken once a
month (or less frequently) and an 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 will be taken more frequently for
patients who are receiving a smaller dose
than is usually prescribed. The doctor can adjust
doses at intervals of 6 to 8 days. An ECG will
be taken at least 1 day after the patient has
started the treatment and 2 and after the
start of the treatment.

Switch over from CV to flecainide tablets. Due
to the near complete oral bioavailability of
flecainide, a CV to 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
administration of the first tablet. Because flecainide has a therapeutic spectrum, close follow-up monitoring is required.

If you take Flecainide Acetate than you
should

If you take more flecainide than you should, tell your doctor or go to hospital immediately and
immediately.

If you forget to take Flecainide Acetate
Take the first dose of flecainide that you have
forgetting. It is only important that you take this
next day. In the latter case, you must not take the
dose that you have forgotten as it may need to
continue to your treatment schedule. Follow the
next day's schedule according to the schedule. Consult your doctor or pharmacist.

Do not take a double dose to make up for a
missed dose.

If you have any further questions on the use
of the medicine, ask your doctor or pharmacist.

Flecainide Acetate tablets

Like all medicines, this medicine can cause side
effects, although not everybody gets them.

Like other antiarrhythmic medicines, patients
can have the side effect of causing a heart rhythm
disorder. This may mean that a patient has
or a new cardiac arrhythmia may develop.

For this reason, the medicine should be
monitored closely. In patients with
structural heart disease and/or a
worsening or a new cardiac arrhythmia may
develop. The risk of these effects is greatest in
patients who are receiving a smaller dose than
the latter case, you must not take the dose that
you have forgotten as it may need to
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next day's schedule according to the schedule. Consult your doctor or pharmacist.

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missed dose.

If you have any further questions on the use
of the medicine, ask your doctor or pharmacist.

Very common (may affect more than 1 in
10 people):

• dizziness
• visual disturbances, such as double vision,
blurred vision and difficulty focusing

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

• flushing
• increased sweating (hyperhidrosis)
• difficulty in controlling movements (ataxia)
• tingling or numbness
• weight gain or loss
• tiredness
• feeling unwell
• feeling light-headed
• sweating
• skin rashes
• fever
• fainting (syncope)

Uncommon (may affect up to 1 in 100 people):

• headache
• nervous disorders e.g. in the arms and legs
• convulsions
• movement disorder (dyskinesia)
• ringing in the ears
• nausea
• speech disorder
• drowsiness
• increased sweating (hyperhidrosis)

Rare (may affect up to 1 in 1000 people):

• seeing things that are not there
• abdominal pain
• skin rashes
• sensitivity to sunlight
• yellowing of the skin or whites of the eyes

Less common side effects

Flecainide Acetate contains

The active substance is flecainide.

Each tablet contains 50 mg or 100 mg of
flecainide acetate.

The other ingredients are cellulose,
microcrystalline, croscarmellose sodium,
cornstarch, magnesium stearate, 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 debossed with '1' and '2' separate by a deep score line on one side and 'CC' on the other side. The tablets are coated with a film

Flecainide Acetate 100mg tablets
White to off-white, round, biconvex tablets debossed with '1' and '2' separate by a deep score line on one side and 'CC' on the other side. The tablets are coated with a film

Flecainide Acetate tablets are available in Csr PVP/PVC - Aluminium foil blister pack and PVP/PVC tablet pack.

Blister: 20, 30, 40, 50, 50, 60, 60, 84, 90 and 100 tablets.

HDPE: 2000 and 1000 tablets.

Not all pack sizes are marketed.

Marketing Authorization Holder

UK - Miltenyi

Aera Blode
Oldbury Road
West End Road
Ruislip HA4 6QD
West End Road
Odyssey Business Park
Malta

Website: www.mhra.gov.uk/yellowcard. By

You can also report side effects directly via
Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard. By

Reporting of side effects

If you get any side effects that worry you or if you change your dose, tell your doctor or pharmacist.

If you think that these side effects are
possibly not side effects but are caused by your
medicine, you can report them in the

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 is the last day of that month.

This medicine does not require any special
storage conditions.

Do not throw away any medicines via
pharmacist how to throw away medicines you

storage conditions.

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