

PROPOSED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

FLECAINIDE 50/100/150/200 CR FORRESTER capsule

Flecainide acetate

FLECAINIDE CR FORRESTER is sugar free

Read all of this leaflet carefully before you start taking FLECAINIDE CR FORRESTER.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FLECAINIDE CR FORRESTER has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What FLECAINIDE CR FORRESTER is and what it is used for

FLECAINIDE CR FORRESTER is an antidysrhythmic which works by controlling the rate and rhythm of your heart.

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FLECAINIDE CR FORRESTER is used to treat:

- Fast, irregular heartbeat (tachycardia and dysrhythmias)
- Unexplained rapid contractions of the muscles in your heart (atrial fibrillation)
- Extra heartbeats that begin in one of your heart's two lower pumping chambers (ventricles).

2. What you need to know before you take **FLECAINIDE CR FORRESTER**

Do not take FLECAINIDE CR FORRESTER if:

- you are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of **FLECAINIDE CR FORRESTER** (see section 6)
- you ever had a heart attack
- you suffer from heart failure, heart block (your heart skips beats), problems with the valves in your heart or some types of heart rhythm disorders

Warnings and Precautions

Take special care with FLECAINIDE CR FORRESTER if:

- you have a conduction disorder (problem with how electrical impulses travel through your heart, which causes it to beat)
- you have a pacemaker
- you have an enlarged heart or a history of any heart problems
- you have a heart condition known as Brugada syndrome (a genetic disease that causes severe disturbances to the rhythm of your heart)
- you have kidney problems
- you have liver problems
- you have an electrolyte imbalance (high or low levels of salt (such

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as potassium) in your blood

- you are elderly - the dosage of FLECAINIDE CR FORRESTER may need to be adjusted.

Children and adolescents

FLECAINIDE CR FORRESTER is not recommended for use in children under 18 years of age.

Other medicines and FLECAINIDE CR FORRESTER

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking any of the following medicines:

- digoxin, beta-blockers (e.g. atenolol, propranolol), amiodarone or quinidine (to treat irregular heartbeats or heart problems)
- antidepressants e.g. fluoxetine, imipramine (to treat depression)
- ritonavir, lopinavir and indinavir (to treat HIV)
- phenytoin, phenobarbital or carbamazepine (to treat seizures fits)
- corticosteroids e.g. prednisolone (for inflammatory conditions such as arthritis)
- laxatives (to treat constipation)
- antipsychotics e.g. clozapine (to treat a mental illness)
- quinine and halofantrine (to treat malaria)
- diuretics (water tablets) e.g. furosemide (to treat high blood pressure)
- antihistamines e.g. mizolastine and terfenadine (to treat allergic reactions)
- cimetidine (to treat stomach ulcers)
- bupropion (to help you stop smoking)

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- warfarin or clopidogrel (to prevent blood clots).

FLECAINIDE CR FORRESTER with food and drink:

The absorption of flecainide acetate is not modified by food.

Pregnancy and breastfeeding:

Do not take FLECAINIDE CR FORRESTER if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding; think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines:

You may experience dizziness, visual disturbances and light-headedness whilst taking FLECAINIDE CR FORRESTER which may impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how FLECAINIDE CR FORRESTER affects you.

3. How to take FLECAINIDE CR FORRESTER

Do not share medicines prescribed for you with any other person.

Always take FLECAINIDE CR FORRESTER exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with FLECAINIDE CR FORRESTER will last.

Your dose will be determined by your doctor according to your condition.

Your treatment will usually be started in hospital under the supervision of your doctor.

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FLECAINIDE CR FORRESTER is taken as a maintenance therapy after your condition is already under control.

If you have the impression that the effect of FLECAINIDE CR FORRESTER is too strong or too weak, tell your doctor or pharmacist.

If you take more FLECAINIDE CR FORRESTER than you should:

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of FLECAINIDE CR FORRESTER:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take FLECAINIDE CR FORRESTER at the next regularly scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

FLECAINIDE CR FORRESTER can have side effects.

Not all side effects reported for FLECAINIDE CR FORRESTER are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking FLECAINIDE CR FORRESTER, please consult your healthcare provider for advice.

If any of the following happens, stop taking FLECAINIDE CR FORRESTER and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat,

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which may cause difficulty in swallowing or breathing

- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLECAINIDE CR FORRESTER. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- unusually slow, fast or irregular heart beat
- heart block which can cause light-headedness, fainting and irregular heart rhythm
- heart attack (signs include pressure, tightness and pain in your chest or arms)
- heart failure (signs include shortness of breath and swelling of the feet or legs due to fluid retention)
- chest pain
- convulsions (fits)
- inflammation of the lungs (signs include weakness, breathlessness, cough and raised temperature)
- liver problems (signs include yellowing of the skin and whites of the eyes (jaundice), nausea, stomach pain).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Frequent side effects:

- Giddiness (feeling that you or your surroundings are moving or spinning), dizziness, light-headedness, pins and needles sensation, problems with co-ordination,

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weakness, numbness or pain in the hands and feet

- Impaired, blurred or double vision
- Shortness of breath
- Unusual weakness or lack of energy, extreme tiredness, fever, swelling of parts of the body (commonly feet, ankles and hands) due to fluid retention.

Less frequent side effects:

- Hallucinations, depression, confusion, anxiety, memory loss, problems sleeping
- Reduced sense of touch, abnormal sweating, fainting, tremor, flushing, sleepiness, headache, seizures, uncontrolled muscle movements
- Small cloudy spots on the eyeball
- Vertigo (feeling of spinning when standing still), tinnitus (ringing in the ears)
- Feeling sick or being sick, constipation, stomach pain or indigestion, loss of appetite, diarrhoea, excess wind
- Loss of hair, itchy skin or rash, sensitivity of the skin to sunlight
- Changes to your blood which will be noticed in a blood test.

Side effects of unknown frequency

- Joint or muscle pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

You can also report side effects to SAHPRA via the **“6.04 Adverse Drug**

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Reaction Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of FLECAINIDE CR FORRESTER.

5. How to store FLECAINIDE CR FORRESTER

- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLECAINIDE CR FORRESTER contains

FLECAINIDE CR FORRESTER is a hard gelatine capsule, filled with extended release mini film coated tablets, allowing controlled release of flecainide acetate.

The active substance is flecainide acetate.

FLECAINIDE 50 CR FORRESTER capsules contains 50 mg flecainide acetate.

FLECAINIDE 100 CR FORRESTER capsules contains 100 mg flecainide acetate.

FLECAINIDE 150 CR FORRESTER capsules contains 150 mg flecainide acetate.

FLECAINIDE 200 CR FORRESTER capsules contains 200 mg flecainide acetate.

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The other ingredients are:

Extended release mini film coated tablets:

Colloidal silicon dioxide, crospovidone, macrogol, magnesium stearate, methacrylic acid-methyl methacrylate copolymer, microcrystalline cellulose, polyvinyl pyrrolidone and talc.

Hard gelatine capsules:

FLECAINIDE 50 CR FORRESTER: The capsule shell contains gelatine and titanium dioxide.

FLECAINIDE 100 CR FORRESTER and FLECAINIDE 150 CR FORRESTER: The capsule shell contains black iron oxide, gelatine and titanium dioxide.

FLECAINIDE 200 CR FORRESTER: The capsule shell contains black iron oxide, red iron oxide, gelatine and titanium dioxide.

What FLECAINIDE CR FORRESTER looks like and contents of the pack

FLECAINIDE 50 CR FORRESTER: Number 4 gelatine opaque capsules with white body and white cap containing white or almost white round micro-tablets.

FLECAINIDE 100 CR FORRESTER: Number 3 gelatine opaque capsules with grey body and white cap containing white or almost white round micro-tablets.

FLECAINIDE 150 CR FORRESTER: Number 2 gelatine opaque capsules with grey body and grey cap containing white or almost white round micro-tablets.

FLECAINIDE 200 CR FORRESTER: Number 1 gelatine opaque capsules with grey body and pink cap containing white or almost white round micro-tablets.

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Transparent PVC/PVDC aluminium foil blister strips containing 6 or 10 capsules.

The blister strips are packed in an outer carton.

Pack size: 6, 10, 12, 30 or 60 capsules

Not all pack sizes may be marketed.

Holder of certificate of registration

Forrester Pharma (Pty) Ltd

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This leaflet was revised in

Date of registration: 29 August 2023

Registration numbers

FLECAINIDE 50 CR FORRESTER: 54/6.2/0421

FLECAINIDE 100 CR FORRESTER: 54/6.2/0422

FLECAINIDE 150 CR FORRESTER: 54/6.2/0423

FLECAINIDE 200 CR FORRESTER: 54/6.2/0424