

**Scheduling Status:****S4****Cardirest 50 tablets  
Cardirest 100 tablets  
Flecainide acetate  
Sugar free****Read all of this leaflet carefully before you start taking Cardirest**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Cardirest 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 Cardirest is and what it is used for
2. What you need to know before you take Cardirest
3. How to take Cardirest
4. Possible side effects
5. How to store Cardirest
6. Contents of the pack and other information

**1. What CARDIREST is and what it is used for**

CARDIREST tablets belong to a group of heart medicines called anti-dysrhythmics.

CARDIREST is used to regulate the rate and rhythm of the heart when it is abnormal. CARDIREST can also be used to maintain a normal heart rhythm after it is normalised by other means.

Your treatment will usually be initiated in hospital.

**2. What you need to know before you take CARDIREST****Do not take CARDIREST:**

- if you are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of CARDIREST (listed in section 6).
- if you suffer from heart failure, had a recent heart attack or have a history of heart attacks.
- if you are pregnant or breastfeeding.

- if you have a long-standing abnormal heart rate or heart disease involving the valves of your heart. If you have problems with the electrical conduction of your heart, CARDIREST will only be given to you if pacing rescue is available.
- if you have a condition called cardiogenic shock, in which your heart cannot pump enough blood to meet the needs of your body.

### Warnings and precautions

Take special care with CARDIREST:

- if you had a heart attack and have an irregular heartbeat and/or rhythm.
- if you have a heart disease involving the structure of your heart.
- if you have a permanent pacemaker or a temporary pacing device.
- if you had heart surgery and experience an irregular, and often rapid, heart rate.
- if you have a slower than normal heart rate or low blood pressure, it should be treated before using CARDIREST.
- if you have high or low potassium levels or any other electrolyte disturbances, it should be treated before using CARDIREST.
- if you have liver problems.
- if you have kidney problems.

CARDIREST may:

- worsen your irregular heart rate by increasing the frequency or severity of it.
- unmask a condition called Brugada Syndrome which is a condition that causes a specific disruption in your heart's normal rhythm, your healthcare provider will discontinue your treatment with CARDIREST if this occurs.

### Children and adolescents

Do not give CARDIREST to children and adolescents under the age of 18 years. There is insufficient evidence of its use in this group.

### Other medicines and CARDIREST

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

**Do not take CARDIREST if you are taking the following medicines used to treat an abnormal heart rate or rhythm:**

- other anti-dysrhythmic medicines.

- medicines belonging to the group of medicines called calcium channel blockers with anti-dysrhythmic activity.

**The following medicines may affect the way CARDIREST works:**

*Medicines inhibiting CYP2D6 (increase plasma concentrations of flecainide)*

- other medicine used to treat heart dysrhythmias or heart problems, such as:
  - cardiac glycosides,
  - beta-blockers such as propranolol (medicines used to reduce the heart's pumping function),
  - calcium-channel blockers such as verapamil (a medicine to lower the blood pressure), or
  - amiodarone; the dose of CARDIREST must be reduced for some patients.
- antihistamines (medicines to treat allergic reactions) such as mizolastine or terfenadine.
- antiviral medicines to treat HIV such as ritonavir, lopinavir or indinavir.
- antidepressants (medicines used to treat depression) such as tricyclic antidepressants, fluoxetine, paroxetine or reboxetine.
- bupropion (a medicine to help you stop smoking).
- cimetidine (medicine to treat stomach ulcers).
- quinine (medicine to treat malaria).
- antipsychotics (medicines to treat mental illness) such as clozapine.

*Medicines inducing CYP2D6 (decrease plasma concentrations of flecainide):*

- anticonvulsants (medicines used to prevent epileptic fits) such as phenytoin, phenobarbital or carbamazepine.

*Medicines lowering or elevating the level of potassium in the blood*

- diuretics (water tablets), laxatives (medicines that stimulate bowel movement) and corticosteroids (adrenal cortex hormones) may lower the level of potassium in the blood causing cardiac toxicity; your doctor may have the amount of potassium in your blood checked.

Electrolyte disturbances (e.g. hypo- and hyperkalaemia) should be corrected before using CARDIREST.

**CARDIREST can have an effect of the following medicines:**

- digoxin (medicine used to treat heart failure and also certain types of irregular heartbeat); CARDIREST may raise the level of digoxin in your blood.

### **CARDIREST with food and drink**

Food does not have an effect on the absorption of CARDIREST.

### **Pregnancy and 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 health care provider for advice before taking this medicine.

Do not take CARDIREST if you are pregnant or breastfeeding your baby.

### **Driving and using machines**

It is not always possible to predict to what extent CARDIREST may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which CARDIREST affects you. CARDIREST may have side effects such as dizziness, double vision or blurred vision.

### **3. How to take CARDIREST**

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

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

The usual starting dose is 50 mg or 100 mg twice a day.

Your doctor will decide on the dose of CARDIREST you should take as your dose depends on the type of abnormal heart rate or rhythm you have.

Your doctor will tell you how long your treatment with CARDIREST will last. Do not stop treatment early. If you have the impression that the effect of CARDIREST is too strong or too weak, tell your doctor or pharmacist.

### **If you take more CARDIREST than you should**

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

Overdose with CARDIREST is a potentially life-threatening medical emergency, seek help immediately. Overdose can also occur due to other medicines taken with CARDIREST (see **Other Medicines and CARDIREST** above).

### **If you forget to take CARDIREST**

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

### **4. Possible side effects**

CARDIREST can have side effects.

Not all side effects reported for CARDIREST are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CARDIREST, please consult your health care provider for advice.

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

- changes to your heartbeat, it starts to pound, or it gets faster or slower
- chest pain
- heart failure/arrest (loss of breathing, and consciousness and loss of heart function)
- heart attack
- difficulty breathing or another breathing or lung problem
- fainting or feeling as if you are going to faint
- yellowing of your skin and eyes (jaundice)
- fits (convulsions)
- itchy, red or swollen skin rash.

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

### **Other possible side effects**

#### *Frequent side effects:*

- giddiness, dizziness and light-headedness
- double vision or blurred vision
- nausea and vomiting
- constipation
- abdominal pain or indigestion
- loss of appetite
- diarrhoea
- flatulence and bloatedness
- skin sensitivity reaction to sunlight
- feeling weak or tired
- lack of energy and strength
- fever
- swelling (fluid retention).

*Less frequent side effects:*

- blood disorders (reduced red and white blood cell count and reduced platelet count)
- confusion and hallucinations
- depression
- anxiety
- difficulty sleeping
- forgetfulness
- numbness, tingling or burning sensation of the skin
- uncontrolled movements or poor coordination, difficulty speaking, unsteady walking
- reduced sense of touch
- excessive sweating and flushed skin
- shaking (tremors)
- sleepiness or a strong desire to sleep or sleep for long periods
- headache
- cloudy spots on your eye (pupil and iris)
- spinning sensation (vertigo)
- ringing in your ears.

*Frequency unknown*

- joint pain and muscle weakness
- arthralgia (pain and swollen joints) and myalgia (aching and weak muscles).

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 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 CARDIREST.

**5. How to store CARDIREST**

Store all medicines out of reach of children.

Store at or below 30 °C, in the original packaging.

## 6. Contents of the pack and other information

### What CARDIREST contains

The active substance is flecainide acetate.

CARDIREST 50 contains 50 mg flecainide acetate per tablet and CARDIREST 100 contains 100 mg flecainide acetate per tablet.

The other ingredients are microcrystalline cellulose (type 101), microcrystalline cellulose (type 102), croscarmellose sodium, pregelatinized starch, hydrogenated vegetable oil (type-1) and magnesium stearate.

### What CARDIREST looks like and contents of the pack

CARDIREST 50 tablets are white to off-white, round shaped tablets, debossed "BPL025" on one side and plain on the other side.

CARDIREST 100 tablets are white to off-white, round shaped tablets, debossed "BPL026" on one side and scored on the other side.

CARDIREST tablets are packed into aluminium/PVDC blister packs with 10 blisters containing 10 tablets each placed in an outer carton. Pack size of 100 tablets.

### Holder of Certificate of Registration:

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