PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

TAMBOCOR CR 100 (controlled release capsule)

TAMBOCOR CR 200 (controlled release capsule)

Flecainide acetate

Sugar free.

Read all of this leaflet carefully before you start taking TAMBOCOR CR

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

1. What TAMBOCOR CR is and what it is used for

TAMBOCOR CR is a cardiac medicine. Flecainide belongs to the group of medicines that work against cardiac dysrhythmia (known as anti-dysrhythmics). It inhibits stimulus conduction in the heart and extends the time during which the heart is at rest, causing the heart to pump normally again.

TAMBOCOR CR is used to regulate the rate and rhythm of the heart.

2. What you need to know before you take TAMBOCOR CR

Do not take TAMBOCOR CR if:

- you are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of TAMBOCOR CR (listed in section 6).
- you suffer from another heart condition, different from the heart condition for which you are taking this medicine (e.g., heart attack, heart failure or heart block (missed heart beats). If you are unsure, of if you would like additional information, consult your doctor or pharmacist.

TAMBOCOR CR is generally not recommended in combination with medicine belonging to class I anti-dysrhythmics, e.g., quinidine, procainamide.

Warnings and precautions

Special care should be taken with TAMBOCOR CR:

- if you have pre-existing dysrhythmia (irregular heartbeat).
- if you have a history of heart failure.
- if you have a permanent pacemaker or temporary pacing electrodes.
- if you suffer from reduced liver function and/or reduced kidney function since the concentration of TAMBOCOR CR in the blood may increase. In that event, your doctor may regularly have the concentration of TAMBOCOR CR in the blood checked.
- if you have pre-existing conduction disorders in the heart.
- if you have too little magnesium in the blood.
- if you suffer from severe bradycardia (very slow heartbeat) or distinct low blood pressure. These conditions should be corrected before using TAMBOCOR CR.
- if you have suffered from cardiac dysrhythmias after heart surgery.
- A lowered or elevated level of potassium in the blood may influence the effect of TAMBOCOR CR. Diuretics, medicines that stimulate bowel movement (laxatives) and adrenal cortex hormones (corticosteroids) may lower the level of potassium in the blood. In that event, your doctor may have the amount of potassium in your blood checked.

Children

TAMBOCOR CR is not recommended in children under 18 years of age.

Other medicines and TAMBOCOR CR

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

If you use certain other medicines along with TAMBOCOR CR, the medicines can sometimes affect the way each other works and/or their side effects (i.e. there may be interactions).

Please consult your doctor, pharmacist or other healthcare professional, for advice if you are taking:

- Any other medicine used to regulate rate and rhythm of the heart.
- Medicines that slow down heart rate and/or conduction such as beta-blockers such as propranolol, amiodarone, verapamil, diltiazem, local anaesthetics.
- Digoxin (a medicine to stimulate the heart).
- Cimetidine (medicine used to treat stomach ulcers).
- Diuretics, laxatives (medicines that stimulate bowel movement) and adrenal cortex hormones (corticosteroids): your doctor may have the amount of potassium in your blood checked.
- Fluoxetine, paroxetine and certain other antidepressants named “tricyclic antidepressants.”
- Phenytoin, phenobarbital and carbamazepine (medicines against epilepsy): the breakdown of flecainide may be accelerated by these substances.
- Clozapine (to treat psychotic disorders).
- Mizolastine and terfenadine (medicines against allergies).
- Quinine (medicine against malaria).
- Ritonavir, lopinavar and indinavir (medicines to treat HIV-infections).
- Bupropion (anti-smoking medicine).

Pregnancy and breastfeeding

Do not take TAMBOCOR CR if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent TAMBOCOR CR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TAMBOCOR CR affects them.

If you suffer from side effects such as dizziness, double vision or blurred vision, or if you feel light in the head, then your ability to react may be reduced. This may be dangerous in situations that demand concentration and attentiveness, such as using the road, handling dangerous machinery or working at heights.

3. How to take TAMBOCOR CR

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

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

The usual starting dose is between 100 mg to 200 mg per day, depending on your condition.

Your doctor will prescribe a personalised dose, adjusted to fit your complaints. Treatment with flecainide will normally be started under medical supervision (if necessary, in the hospital).

If you take more TAMBOCOR CR than you should:

Overdosage with TAMBOCOR CR is a potentially life-threatening medical emergency. In the event of overdosage, contact your doctor or go to the nearest hospital or poison control centre immediately.

If you forget to take TAMBOCOR CR

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

If you stop taking TAMBOCOR CR

If you suddenly stop taking TAMBOCOR CR the cardiac dysrhythmia will no longer be controlled as intended. So never stop using it without your doctor knowing.

4. POSSIBLE SIDE EFFECTS

TAMBOCOR CR can have the following side effects.

Not all side effects reported for TAMBOCOR CR are included in this leaflet. Should your general health worsen or if you experience untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent side effects:

- feeling dizzy
- lightheaded
- double vision, vision impairment or blurring of vision
- more frequent occurrence of pre-existing arrhythmia (irregular heartbeat)
- shortness of breath
- weakness; fatigue
- fever
- fluid in the tissues (oedema)

Less frequent side effects:

- an abnormal sensation, typically tingling or pricking (‘pins and needles’)
- difficulty in controlling movements (ataxia)
- a partial or total loss of sensation in a part of your body
- abnormally excessive sweating
- fainting or passing out
- a rhythmic shaking movement in one or more parts of your body (tremors)
- flushing
- sleepiness, headache
- weakness, numbness and pain, usually in your hands and feet
- seizures
- involuntary, erratic, writhing movements of the face, arms, legs or trunk (dyskinesia)
- irregular heartbeat with increased heartbeat
- inflammation of lung tissue; lung disease that occurs when lung tissue becomes damaged and scarred

- nausea, vomiting, constipation, abdominal pain, decreased appetite, diarrhoea, indigestion, flatulence
- yellowing of the skin (jaundice)
- liver failure
- allergic skin reactions, including rash and hair loss
- sensitivity to the effects of sunlight.
- joint and 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 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 TAMBOCOR CR.

5. How to store TAMBOCOR CR

Store the tablets in a cool, dry place at or below 30 °C.

In order to protect from light, keep blister pack in the outer carton.

Keep all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TAMBOCOR CR contains

The active substance is flecainide.

The other ingredients are microcrystalline cellulose, methacrylic acid – methyl methacrylate copolymer (1:2), polyethylene glycol 400 (Macrogol 400), talc, gelatin, titanium oxide, iron oxide black, erythrosine, shellac.

What TAMBOCOR CR looks like and contents of the pack

TAMBOCOR CR 100: Hard, white to off-white beadlets in size 3 hard gelatin capsule with a light grey cap and an opaque white body, printed TR on the cap and 100 on the body, in black.

TAMBOCOR CR 200: Hard, white to off-white beadlets in size 1 hard gelatin capsule with a light grey cap and an opaque pink body, printed TR on the cap and 200 on the body, in black.

TAMBOCOR CR are controlled release capsules and are packed in:

Blister pack of 15, 30 and 60 tablets.

Blisters are made of clear UPVC / PVC with aluminium foil backing.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, South Africa.

Tel: +27 (0)11 087 0000

This leaflet was last revised on

05 September 2021

Registration number

TAMBOCOR CR 100: 37/6.2/0199

TAMBOCOR CR 200: 37/6.2/0201

Access to the corresponding Professional Information

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals (Pty) Ltd.