PROPOSED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

TEMPACIN 50/100/150/200 CR capsule

Flecainide acetate

TEMPACIN CR is sugar free

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

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

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

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

TEMPACIN CR 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 TEMPACIN CR

Do not take TEMPACIN CR if:

- you are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of TEMPACIN CR (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 TEMPACIN CR 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

as potassium) in your blood

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

Children and adolescents

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

Other medicines and TEMPACIN CR

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)

- warfarin or clopidogrel (to prevent blood clots).

TEMPACIN CR with food and drink:

The absorption of flecainide acetate is not modified by food.

Pregnancy and breastfeeding:

Do not take TEMPACIN CR 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 TEMPACIN CR 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 TEMPACIN CR affects you.

3. How to take TEMPACIN CR

Do not share medicines prescribed for you with any other person.
Always take TEMPACIN CR 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 TEMPACIN CR 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.

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

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

If you take more TEMPACIN CR 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 TEMPACIN CR:

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 TEMPACIN CR at the next regularly scheduled time.

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

4. Possible side effects

TEMPACIN CR can have side effects.

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

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

If any of the following happens, stop taking TEMPACIN CR 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,

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 TEMPACIN CR. 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,

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 of 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 TEMPACIN CR.

5. How to store TEMPACIN CR

- 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 TEMPACIN CR contains

TEMPACIN CR 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.

TEMPACIN 50 CR capsules contains 50 mg flecainide acetate.

TEMPACIN 100 CR capsules contains 100 mg flecainide acetate.

TEMPACIN 150 CR capsules contains 150 mg flecainide acetate.

TEMPACIN 200 CR capsules contains 200 mg flecainide acetate.

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:

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

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

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

What TEMPACIN CR looks like and contents of the pack

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

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

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

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

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

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This leaflet was revised in

Date of registration: 29 August 2023

Registration numbers

TEMPACIN 50 CR: 54/6.2/0421

TEMPACIN 100 CR: 54/6.2/0422

TEMPACIN 150 CR: 54/6.2/0423

TEMPACIN 200 CR: 54/6.2/0424