PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TICANARY 90 mg film-coated tablets

Ticagrelor

Contains sugar alcohol: 126 mg mannitol per tablet.

Read all of this leaflet carefully before you start taking TICANARY 90

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TICANARY 90 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 TICANARY 90 is and what it is used for

TICANARY 90 contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelet medicines. Platelets are very small fragments in the blood that clump together during blood clotting. TICANARY 90 helps prevent this clumping and reduces the risk of blood clots

forming.

TICANARY 90 is used in combination with low dose acetylsalicylic acid (aspirin) in adults to help prevent blood clots and reduce the risk of having or dying from conditions caused by blood clots. This includes:

- a stroke
- heart attack, or
- heart or blood vessel problems.

It reduces the chances of you having a heart attack, stroke or dying from a disease related to your heart or blood vessels.

2. What you need to know before you take TICANARY 90

Do not take TICANARY 90:

- if you are hypersensitive (allergic) to ticagrelor or to any of the other ingredients of TICANARY 90 listed in section 6 of this leaflet;
- if you are actively bleeding due to a medical condition, such as bleeding in your stomach or gut from an ulcer or bleeding in your skull or brain;
- if you have had a stroke caused by bleeding in the brain;
- if you have severe liver disease;
- if you are taking any of the following medicines:
    - ketoconazole and itraconazole (used to treat fungal infections)
    - clarithromycin (used to treat bacterial infections)
    - nefazodone (an antidepressant)
    - ritonavir and atazanavir (used to treat HIV infection and AIDS)
    - rifampicin (used to treat tuberculosis (TB))
    - carbamazepine and phenytoin (used to treat epilepsy)
    - phenobarbital (used to treat anxiety and certain types of seizures (fits));
- if you were born with a bleeding disorder (inherited bleeding disorder).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking TICANARY 90 if you have any of the following:

- an increased risk of bleeding because of:
  - a recent serious injury
  - recent surgery (including dental work, ask your dentist about this)
  - a condition that affects blood clotting
  - recent bleeding from your stomach or gut (such as a stomach ulcer or colon ‘polyps’)
  - taking any of the following medicines:
    - non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, celecoxib and naproxen
    - blood thinners such as warfarin
    - medicines that help dissolve blood clots.

Also tell your doctor:

- if you are due to have surgery (including dental work) at any time while taking TICANARY 90. This is because of the increased risk of bleeding. Your doctor may want you to stop taking TICANARY 90 5 days prior to surgery;
- if you had a stroke in the past;
- if you have had any problems with your liver or have previously had any disease which may have affected your liver;
- if your heart rate is abnormally low (usually lower than 60 beats per minute) and you do not already have in place a device that paces your heart (pacemaker);
- if you have asthma or other lung problems or breathing difficulties;
- have a history of gout;
- if you have had a blood test that showed more than the usual amount of uric acid.

If you are taking both TICANARY 90 and heparin

Your doctor may require a sample of your blood for diagnostic tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both

TICANARY 90 and heparin, as TICANARY 90 may affect the diagnostic test.

Thrombotic thrombocytopenic purpura (TTP)

TICANARY 90 may cause thrombotic thrombocytopenic purpura (TTP) (a rare disorder that causes blood clots to form in small blood vessels throughout the body). Rare cases of TTP were reported in patients taking TICANARY 90. This condition can cause serious complications or even death. Tell your health care provider right away if you experience some or all of the following symptoms:

- fever;
- purplish spots on the skin or in the mouth (purpura);
- yellowing of the skin or eyes (jaundice);
- unexplained extreme tiredness or confusion.

Children and adolescents

TICANARY 90 is not indicated for use in children and adolescents under 18 years of age as safety and efficacy have not been established in this age group.

Other medicines and TICANARY 90

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
This is because TICANARY 90 can affect the way some medicines work and some medicines can have an effect on TICANARY 90.

It is especially important to tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin (used to treat tuberculosis (TB));
- phenytoin, carbamazepineand phenobarbital (used to control seizures)
- dexamethasone (a corticosteroid used in a wide range of conditions for its anti-inflammatory and immunosuppressant effects);

- more than 40 mg daily of either simvastatin or lovastatin (medicines used to treat high cholesterol);
- ciclosporin (used to lessen your body's defenses);
- quinidine (used to treat abnormal heart rhythms)
- verapamil and diltiazem (used to treat high blood pressure or chest pain);
- morphine and other opioids (used to treat severe pain);
- cisapride (used to treat heartburn);
- ergot alkaloids (used to treat migraines and headaches);
- digoxin (used to treat heart failure);
- selective serotonin reuptake inhibitors (SSRIs) used to treat depression, such as paroxetine, sertraline and citalopram.

TICANARY 90 with food and drink

TICANARY 90 may be taken with or without food.

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 TICANARY 90.

It is not recommended to use TICANARY 90 if you are pregnant or may become pregnant. Women should use appropriate contraceptive measures to avoid pregnancy while taking TICANARY 90.

It is not recommended to use TICANARY 90 if you are breastfeeding.

Driving and using machines

TICANARY 90 can cause side effects, such as dizziness and confusion. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how TICANARY 90 affects you.

3. How to take TICANARY 90

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

Always take TICANARY 90 exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will advise you on the dose to be taken for your specific condition.

Your doctor will tell you how long your treatment with TICANARY 90 will last. Do not stop treatment with TICANARY 90 unless your doctor tells you to.

The usual starting dose is two tablets at the same time (loading dose of 180 mg). After this starting dose, the usual dose is one tablet of 90 mg twice a day for up to 12 months unless your doctor tells you differently.

Your doctor will usually also tell you to take aspirin (used to prevent blood clotting) . Your doctor will tell you how much to take (usually between 75 – 150 mg daily).

Swallow the tablet with a drink of water. TICANARY 90 can be taken with or without food. Try to take the tablets at the same time every day to have the best treatment effect.

If you have the impression that the effect of TICANARY 90 is too strong or too weak, tell your doctor or pharmacist.

If you take more TICANARY 90 than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. You or a child in your care may require medical attention. Take the medicine pack with you.

Symptoms of TICANARY 90 overdose include excessive bleeding, shortness of breath and pauses in heartbeat.

If you forget to take TICANARY 90

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Then continue with your normal schedule. Do not take a double dose to make

up for a forgotten dose.

If you stop taking TICANARY 90

Do not stop taking TICANARY 90 without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early. If you have any further questions on the use of TICANARY 90, ask your doctor or pharmacist.

4. Possible side effects

TICANARY 90 can have side effects.

Not all side effects reported for TICANARY 90 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TICANARY 90, please consult your health care provider for advice.

If any of the following happens, stop taking TICANARY 90 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and 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 TICANARY 90. 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:

- bleeding, including:
  - bleeding that is severe or that you cannot control;
  - unexpected bleeding/bruising or bleeding that lasts a long time;
  - bleeding in your brain or in your scull (sudden numbness or weakness of your arm, leg or face,

especially if only on one side of the body,- sudden confusion, difficulty speaking or understanding others, sudden difficulty in walking or loss of balance);

- blood in your eyes or ears;
- vomiting blood or blood in your spit when coughing;
- bright/red blood in the stools (tarry stools);
- blood in your urine;
- bleeding occurring after your operation including bruising and swelling, blood or liquid leaking from the surgical wound/incision (wound secretion) or injection site;
- bleeding in your muscle/s or joints causing painful swelling;

- signs of a blood clotting problem called thrombotic thrombocytopenic purpura (TTP) such as:
  - fever and purplish spots (called purpura) on your skin or in your mouth, with or without yellowing of your skin or eyes (jaundice), unexplained extreme tiredness or confusion.

Tell your doctor if you notice any of the following:

Frequent side effects:

- high level of uric acid in your blood when blood tests are done;
- severe pain and swelling in your joints – signs of gout;
- headaches, dizziness;
- vertigo (sensation of spinning or swaying);
- low blood pressure (dizziness or light-headedness, or blurred vision);
- dyspnoea (shortness of breath);
- nosebleed;
- abdominal pain, diarrhoea, nausea (feeling sick), vomiting (being sick), indigestion, constipation;
- bleeding from your stomach lining (ulcer), bleeding gums
- increased creatinine levels when blood tests are done;
- bleeding from cuts (for example while shaving) and wounds more than is normal.

Less frequent side effects:

- feeling confused;
- tingling or numbness of your hands and feet (pins and needles);
- vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding.

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. This includes any possible side effects not listed in this leaflet. 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 TICANARY 90.

5. How to store TICANARY 90

- Store at or below 25 °C.
- Keep the blister strips in the 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 or blister strip.
- 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 TICANARY 90 contains

The active substance in TICANARY 90 is ticagrelor.

Each film-coated tablet contains 90 mg ticagrelor.

The other ingredients are the:

Tablet core:

Calcium hydrogen phosphate dihydrate, hydroxypropyl cellulose, magnesium stearate and mannitol [E421].

Film-coating:

Opadry yellow (containing hypromellose [E464], iron oxide yellow [E172], polyethylene glycol [E1521], talc [E553b] and titanium dioxide [E171]).

What TICANARY 90 looks like and contents of the pack

Yellow coloured, round, biconvex, film-coated tablets, debossed with "90 & M" on one side and plain on other side, free from physical defects.

PVC/PVDC/aluminium blister strips containing 14 tablets, packed into an outer container.

Pack size: 56 tablets.

Holder of certificate of registration

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Unit 6, Ground Floor

10 Church Street

Durbanville

7551

Tel: 087 551 3245

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