PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

BRILINTA® 90 mg Film-coated Tablets

Ticagrelor

Contains sugar: mannitol 126 mg

Read all of this leaflet carefully before you start taking BRILINTA

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

1. What BRILINTA is and what it is used for

BRILINTA belongs to a group of medicines called anti-platelet agents.

BRILINTA is only to be used in adults. You have been given BRILINTA because you have had:

- a heart attack, or
- unstable angina (angina or chest pain that is not well controlled).

BRILINTA reduces the chances of having another heart attack or of dying from a disease related to your heart or blood vessels.

How BRILINTA works:

BRILINTA helps stop the clumping of platelets in blood vessels. This reduces the chance of a blood clot forming that can block a blood vessel.

Your doctor will usually tell you to also take aspirin.

2. What you need to know before you take BRILINTA

Do not take BRILINTA:

- if you are hypersensitive (allergic) to ticagrelor or any of the other ingredients of BRILINTA listed in section 6.
- if you have known problems with bleeding, such as bleeding in your stomach or gut from an ulcer.
- if you have severe liver disease.
- if you have had a stroke caused by bleeding in the brain.
- if you have any inherited bleeding disorders.
- if you are taking any of the following medicines:
  - ketoconazole or itraconazole (used to treat fungal infections)
  - clarithromycin (an antibiotic)
  - ritonavir or atazanavir (used to treat HIV)
  - rifampicin (an antibiotic used to treat infections such as TB)
  - phenytoin, carbamazepine or phenobarbitone (used to treat epilepsy or seizures).

Do not take BRILINTA if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking BRILINTA.

Warnings and precautions

Take special care with BRILINTA:

Check with your doctor or pharmacist before taking BRILINTA:

- if you have an increased risk of bleeding because of:
  - a recent serious injury
  - recent surgery (including dental procedures)

- recent bleeding from your stomach or gut (such as a stomach ulcer or colon 'polyps')
- liver problems.

- if you are taking certain medicines (see "Other medicines and BRILINTA" below).
- if you are due to have surgery (including dental procedures) at any time while taking BRILINTA. This is because of the increased risk of bleeding. Your doctor may want you to stop taking BRILINTA for a short period.
- if you are at high risk for certain types of heart conditions in which your heartbeat is irregular or too slow.
- if you develop shortness of breath or already suffer from shortness of breath which has gotten worse since starting BRILINTA.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking BRILINTA.

Children and adolescents

BRILINTA is not recommended for children and young people under 18 years.

Other medicines and BRILINTA

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that increase your risk of bleeding:

- 'oral anticoagulants' often referred to as "blood thinners" such as warfarin.
- 'fibrinolytics' often referred to as "clot-dissolvers" such as streptokinase.
- non-steroidal anti-inflammatory drugs (NSAIDs).

Other medicines you should mention include:

- antifungal medications such as ketoconazole and itraconazole.
- antibiotics such as clarithromycin and rifampicin.
- anti-HIV medicines such as ritonavir and atazanavir.
- medicines used to treat epilepsy, such as phenytoin, carbamazepine or phenobarbitone.
- a medicine called digoxin which is used to treat certain heart conditions.
- medicines used to treat cholesterol called simvastatin or lovastatin, especially if the dose that you are taking is 40 mg or more.
- a medicine used to prevent transplant rejection called ciclosporin.

BRILINTA with food and drink

BRILINTA may be taken with or without food.

Pregnancy and breastfeeding

Safety of BRILINTA during pregnancy and breastfeeding has not been established.

It is not recommended to use BRILINTA if you are pregnant or may become pregnant. Women should use appropriate contraceptive measures to avoid pregnancy while taking this medicinal product.

Talk to your doctor before taking BRILINTA if you are 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.

Driving and using machines

BRILINTA may affect your ability to drive or use machines. You are being treated because you had a heart attack or unstable angina and you may experience dizziness and confusion. If you have these symptoms, you should be cautious if you drive or use machines.

BRILINTA contains mannitol

Your tablet contains mannitol (sugar), which may cause a problem in a small number of patients who are

intolerant to mannitol.

3. How to take BRILINTA

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

Always take BRILINTA as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 1 tablet twice a day. The treatment is normally recommended for at least 12 months.

Your doctor will usually also tell you to take acetylsalicylic acid (aspirin). Your doctor will tell you how much to take.

- You can take the tablet with or without food.
- Take your dose at around the same time every day. For example, one in the morning and one in the evening.
- You can check the day when you last took a tablet of BRILINTA by looking at days on the blister. There is a sun (for the morning) and a moon (for the evening). This will tell you whether you have taken the dose.

If you have trouble swallowing the tablet(s)

If you have trouble swallowing the tablet(s) you can crush them and mix with water as follows:

- Crush the tablet(s) to a fine powder.
- Pour the powder into half a glass of water.
- Stir and drink immediately.
- To make sure that there is no medicine left, rinse the empty glass with another half a glass of water and drink it.

If you take more BRILINTA than you should

If you take more BRILINTA than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you. You may be at an increased risk of bleeding.

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

If you forget to take BRILINTA

- Take your next dose as normal.
- Do not take a double dose (2 doses at the same time) to make up for the forgotten dose.

If you stop taking BRILINTA

Do not stop taking BRILINTA without consulting with your doctor.

Take it for as long as your doctor keeps prescribing it. If you want to stop taking BRILINTA consult your doctor first. This is because the risks and the benefits of BRILINTA are based on you taking it as long as your doctor thinks it is necessary.

If you have further questions on the use of BRILINTA, ask your doctor or pharmacist.

4. Possible side effects

BRILINTA can have side effects.

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

Consult your doctor without delay if you notice any of the following – you may need urgent medical treatment:

- **signs of bleeding such as:**
  - bleeding that is severe or that you cannot control
  - bleeding that lasts a long time

- pink, red or brown urine
- vomiting red blood or your vomit looks like “coffee grounds”
- red or black stools (looks like tar)
- coughing up blood or blood clots.

- **signs of a stroke such as:**
  - sudden numbness or weakness of your arm, leg or face
  - sudden confusion, difficulty in speaking or understanding others
  - sudden difficulty in walking or loss of balance or co-ordination
  - suddenly feeling dizzy or sudden severe headache with no known cause.

- **fainting (syncope)** – a temporary loss of consciousness due to sudden drop in blood flow to the brain caused by a decrease in your blood pressure.

- **Signs of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) such as:**
  - fever and purplish spots (called purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion.

TTP has been very rarely reported for patients treated with ticagrelor (frequency cannot be estimated from the available data).

Discuss with your doctor if you notice any of the following:

- **feeling short of breath –** It is a frequent side effect of BRILINTA.

If the feeling of shortness of breath gets worse or persists, tell your doctor. Your doctor will advise you what to do.

Other possible side effects:

Frequent side effects:

- an increase in the level of uric acid in the blood
- bruising, bleeding into the skin

- nosebleed
- feeling dizzy or like the room is spinning
- diarrhoea
- feeling sick (nausea)
- itching
- severe pain and swelling in your joints – these may be signs of gout
- feeling dizzy or light-headed or having blurred vision – these are signs of low blood pressure
- bleeding caused by blood disorder
- bleeding after surgery of from cuts (e.g. while shaving) and wounds that is more than normal
- bleeding from your stomach lining (ulcer)
- bleeding gums.

Less frequent side effects:

- confusion
- vaginal bleeding that is heavier or happens at different times than your normal period (menstrual) bleeding
- bleeding from a tumour
- blood in your ear
- internal bleeding, that may cause dizziness or light-headedness
- bleeding into joints and muscles causing painful swelling.

Frequency not known side effects:

- Slow heart rate (bradyarrhythmia)
- Breathing stop and start (gasping or choking noises) while sleeping (sleep apnoea)
- Allergic reactions that may include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- Rash.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist promptly, but do not stop taking BRILINTA until you have spoken to

them.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you help provide more information on the safety of BRILINTA.

5. How to store BRILINTA

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not remove the blisters from the outer carton until required for use.
- Do not use BRILINTA after the expiry date, which is stated on the blister and carton after expiry. The expiry date refers to the last day of that month.

How to dispose of BRILINTA:

- Take all unused or expired medicines to your pharmacist, doctor or other healthcare professional.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

6. Contents of the pack and other information

What BRILINTA contains

The active substance is ticagrelor. Each tablet contains 90 mg ticagrelor.

The other ingredients are:

Dibasic calcium phosphate, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, polyethylene glycol 400, sodium starch glycolate, talc and titanium dioxide.

What BRILINTA looks like and contents of the pack

BRILINTA tablets are round, biconvex, yellow, film-coated tablets marked with a “90” above “T” on one

side and plain on the other side.

BRILINTA is packed in clear PVC/PVDC aluminium foil blister packs in cartons of 14, 56, 60, 168 or 180 tablets.

Packs of 14, 56 and 168 tablets contain 14 tablets per blister.

Packs of 60 and 180 tablets contain 20 tablets per blister.

Not all pack sizes may be marketed.

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