

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Brilinta® 90 mg Tablet (Ticagrelor 90 mg per tablet)

Read this entire 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 or your pharmacist.
- BRILINTA has been prescribed for you personally and you should not share your medicine with other people or pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. 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.

Contains sugar.

2. WHAT BRILINTA IS USED FOR:

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

You have been given BRILINTA because you have had:

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

How BRILINTA works:

BRILINTA affects blood components called 'platelets'.

- Platelets are very small cells in your blood.
- The function of platelets is to help stop bleeding.

When a blood vessel is damaged, platelets clump together to help form a blood clot which stops the bleeding.

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. This means that BRILINTA reduces the chances of you having another heart attack or a stroke.

Your doctor will usually tell you to also take aspirin. This is another medicine which affects platelets.

3. BEFORE TAKING BRILINTA:

Do not take BRILINTA if:

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

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.
- you are taking certain medicines (see ‘Taking other medicines with BRILINTA’ below)
- 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
- you are at high risk for certain types of heart conditions in which your heart beat is irregular or too slow
- 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.

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

Taking 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.

You should not receive BRILINTA when you are pregnant or breastfeeding your baby.

Talk to your doctor before taking BRILINTA if you are pregnant, may become pregnant or are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking BRILINTA.

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.

Important information about some of the ingredients of BRILINTA:

BRILINTA contains mannitol which may have a mild laxative effect.

Taking other medicines with BRILINTA:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription, dietary supplements and herbal remedies. This is because BRILINTA can affect the way some medicines work, and some medicines can have an effect on BRILINTA.

In particular, tell you 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
- antiviral medicines such as nefazadone, ritonavir and atazanavir
- medicines used to treat epilepsy, such as rifampicin, phenytoin, carbamazepine or phenobarbital
- 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.

If you are taking medicines on a regular basis, including complementary or traditional medicines, using BRILINTA with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

4. HOW TO TAKE BRILINTA:

- follow your doctor, pharmacist, or other healthcare professional's instructions on how to take BRILINTA and ask them if you are unsure
- do not share medicines prescribed for you.

How much to take:

- the starting dose is 2 tablets at the same time. This dose will usually be given to you in the hospital.
- after that, 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.

How to take BRILINTA:

- swallow each tablet whole with a drink of water
- you can take the tablet with or without food
- take your dose at around the same time every day. For example, 1 in the morning and 1 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 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 an overdose, 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 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 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.

5. POSSIBLE SIDE-EFFECTS:

BRILINTA can cause side-effects. The following side-effects may happen with BRILINTA:

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

- **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.
- **bleeding** – some bleeding occurs frequently. Severe bleeding is less frequent but can be life threatening. Bleeding of many different kinds can be increased, for example:
 - blood in your urine
 - black stools or blood in your stools
 - blood in your eye.

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:

- an increase in the level of uric acid in the blood
- bruising
- nosebleed
- headache
- feeling dizzy or like the room is spinning
- stomach pain
- constipation, diarrhoea or indigestion
- feeling or being sick
- rash
- itching

Less frequent:

- confusion
- a tingling feeling
- inflamed stomach (gastritis)

If any of the side-effects gets serious, or if you notice any side-effects not listed in this leaflet, please consult your doctor or pharmacist.

Not all side-effects reported for BRILINTA are included in this leaflet. Should your general health worsen while taking BRILINTA, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORAGE AND DISPOSAL INFORMATION:

How to store BRILINTA:

- 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

- keep all medicines out of reach and sight of children.

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 will help to protect the environment.

7. PRESENTATION:

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

The packs contain blisters of either 14 or 20 tablets each.

8. IDENTIFICATION:

BRILINTA tablets are round, biconvex, yellow, film-coated tablets marked with a “90” above “T” on one side and plain on the other side.

9. REGISTRATION NUMBER:

44/8.2/1041

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION:**

AstraZeneca Pharmaceuticals (Pty) Limited

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11. DATE OF PUBLICATION OF PATIENT INFORMATION LEAFLET:

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