

BRILINTA FILM-COATED TABLET

Ticagrelor (90mg)

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What Brilinta is used for

Brilinta contains a medicine called ticagrelor. This 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 you having a stroke or of having another heart attack or of dying from cardiovascular disease.

How Brilinta works

Brilinta affects cells called ‘platelets’

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

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

However, clots can also form **inside** a damaged blood vessel. This can be very dangerous because:

- the clot can cut off the blood supply completely - this can cause a heart attack (myocardial infarction) or stroke.
- the clot can partly block the blood vessels to the heart - this reduces the blood flow to the heart. This can cause chest pain which comes

and goes (called ‘unstable angina’).

Brilinta helps stop the clumping of platelets. 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 having a stroke or of dying from cardiovascular disease.

Your doctor will usually also tell you to take acetylsalicylic acid. This is a substance present in many medicines used to prevent blood clotting.

Before you use Brilinta

- When you must not use it:

- If you are allergic (hypersensitive) to ticagrelor or any of the other ingredients of Brilinta (listed in Section Product Description).
- If you have 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.

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.

- Before you start to use it

Check with your doctor, pharmacist or dentist before taking Brilinta if:

- You have an increased risk of bleeding because of:
 - a recent serious injury
 - recent surgery (including dental work)
 - recent bleeding from your stomach or gut (such as a stomach ulcer or colon ‘polyps’)
 - moderate liver problems
- You are due to have surgery (including dental work) 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 time.

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

Use in children

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

-Taking other medicines

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 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’ which include warfarin.
- ‘fibrinolytics’ often referred to as ‘clot-dissolvers’ which include streptokinase and alteplase.
- other medicines you should mention include ketoconazole, clarithromycin, nefazadone, ritonavir and atazanavir.

Refer to your doctor or pharmacist for a more complete list of medicines that will interact with Brilinta.

How to use Brilinta

-How much to use

The usual dose is one tablet twice a day.

-When to use it

You can take the tablet with or without food.

-How long to use it

The treatment is recommended for at least 12 months unless your doctor tells you differently.

-If you forget to use it

- You can check when you last took a tablet of Brilinta by looking 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 forget to take a dose, just take your next dose as normal.
- Do not take a double dose (two doses at the same time) to make up for the forgotten dose.

-If you use too much (overdose)

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.

While you are using it

-Things you must do

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

-Things you must not do

Do not stop taking Brilinta without talking to your doctor. Take it for as long as your doctor keeps prescribing it. If you want to stop, it is important that you talk to your doctor first. This is because the risks and the benefits of Brilinta are based on you taking it on a regular basis.

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

-Things to be careful of

Pregnancy

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 breast-feeding. Your doctor will discuss with you the benefits and risks of taking Brilinta during this time. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

Brilinta is not likely to affect your ability to drive or use machines.

Side effects

Like all medicines, Brilinta can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

See a doctor straight away 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, especially if only on one side of the body
 - sudden confusion, difficulty 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

These are signs of a kind of stroke caused by bleeding into the brain. This is uncommon (affects less than 1 in 100 people).

- Bleeding – some bleeding is common (affects less than 1 in 10 people). However, severe bleeding is uncommon (affects less than 1 in 100 people), but can be life threatening. Bleeding risk of many different kinds can be increased, for example:
 - nosebleed (common)
 - blood in your urine (uncommon)
 - black stools or blood in your stools (common)

- blood in your eye (uncommon)
- coughing up or bringing up blood (uncommon)
- vaginal bleeding that is heavier, or happens at different times, to your normal period (menstrual) bleeding (uncommon)
- bleeding after surgery or from cuts and wounds that is more than normal (common)
- bleeding from your stomach lining (ulcer) (uncommon)
- bleeding gums (uncommon)
- blood in your ear (rare)
- internal bleeding (rare)
- bleeding into joints causing painful swelling (rare)

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

- **Feeling short of breath** - this is common (affects less than 1 in 10 people). It might be due to your heart disease or another cause, or it might be a side effect of Brilinta. If your feeling of shortness of breath gets worse or lasts a long time, tell your doctor. Your doctor will decide if it needs treatment or further investigations.

Other possible side effects:

Common (affects less than 1 in 10 people)

- Bruising

Uncommon (affects less than 1 in 100 people)

- Headache
- Feeling dizzy or like the room is spinning
- Abdominal pain
- Diarrhoea or indigestion
- Feeling or being sick
- Rash
- Itching
- Inflamed stomach (gastritis)
- Allergic reaction - a rash, itching, or a swollen face or swollen lips/tongue may be signs of an allergic reaction (see 'BEFORE YOU TAKE BRILINTA')

Rare (affects less than 1 in 1000 people)

- An increase in the level of uric acid in the blood.
- Constipation
- Confusion
- A tingling feeling

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling TEL: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage & Disposal of Brilinta

-Storage

- Do not store above 30°C.
- Keep out of the reach and sight of children
- Do not use Brilinta after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

-Disposal

- 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.

Product Description

-What it looks like

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

Brilinta is available in standard blisters in cartons of 14 tablets (sample packs) & 60 tablets (sales pack).

-Ingredients

- The active substance is ticagrelor. Each film-coated tablet contains 90 mg of ticagrelor.
- The other ingredients are:
Tablet Core: mannitol, dibasic calcium phosphate, sodium starch glycolate, hydroxypropyl cellulose, magnesium stearate

Tablet film coating: hypromellose, titanium dioxide, talc, polyethylene glycol 400, and ferric oxide yellow.

-MAL number:

MAL20112115AR

Manufacturer

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15185 Södertälje, Sweden.

Product Registration Holder

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