AstraZeneca

Brilinta®

Ticagrelor 60 mg or 90 mg Film Coated Tablets.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Brilinta**. It does not contain all the information that is known about **Brilinta**.
It does not take the place of talking to your doctor or pharmacist.
All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Brilinta** against the benefits they expect it will have for you.
If you have any concerns about taking this medicine, ask your doctor or pharmacist.
Keep this leaflet with the medicine. You may need to read it again.

What Brilinta is used for

Brilinta in combination with aspirin is to be used in adults only. 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 contains the active substance called ticagrelor. This belongs to a group of medicines called anti-platelet medicines.
Brilinta affects cells called 'platelets' (also called thrombocytes). These very small blood cells help stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged. However, platelets can also form clots inside diseased blood vessels in the heart and brain. This can be very dangerous because:

- the clot can cut off the blood supply completely - this can cause a heart attack (myocardial infarction), or
- the clot can partly block the blood vessels to the heart - this reduces the blood flow to the heart and 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 reduce blood flow.
This medicine is only available with a doctor's prescription.

Before you use Brilinta

When you must not use it
Do not take **Brilinta** if:

- You are allergic to ticagrelor or any of the other ingredients of **Brilinta** (listed in Product Description)
- You have problems with bleeding, such as bleeding in your stomach or gut from an ulcer
- You have severe liver disease
- You are taking any of the following medicines: ketoconazole (used to treat fungal infections), clarithromycin (used to treat bacterial infections), nefazodone (an antidepressant), ritonavir and atazanavir (used to treat HIV infection and AIDS)
- 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**.

Take special care with Brilinta

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)
  - you have a condition that affects blood clotting
  - 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** 5 days prior to surgery
- 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)
- You have asthma or other lung problem or breathing difficulties
- You have had a blood test that showed more than the usual amount of uric acid

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

Children and adolescents

Brilinta is not recommended for children and adolescents 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**.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- rosuvastatin or more than 40 mg daily of either simvastatin or lovastatin (medicines used to treat high cholesterol)
- rifampicin (an antibiotic), phenytoin, carbamazepine and phenobarbital (used to control seizures), digoxin (used to treat heart failure), cyclosporin (used to lessen your body's defences), quinidine and diltiazem (used to treat abnormal heart rhythms), beta blockers and verapamil (used to treat high blood pressure)

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 called 'clot dissolvers', which include streptokinase and alteplase
- non-steroidal anti-inflammatory drugs (abbreviated as NSAIDs) often taken as pain killers such as ibuprofen and naproxen
- selective serotonin reuptake inhibitors (abbreviated as SSRIs) taken as antidepressants such as paroxetine, sertraline and citalopram
- other medicines such as ketoconazole (used to treat fungal infections), clarithromycin (used to treat bacterial infections), nefazodone, (an antidepressant), ritonavir and atazanavir (used to treat

HIV infection and AIDS), cisapride (used to treat heartburn), ergot alkaloids (used to treat migraines and headaches)

Taking Brilinta with food and drink
You can take **Brilinta** with or without food.

Pregnancy and breast-feeding
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 medicine. 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.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Brilinta is not likely to affect your ability to drive or use machines. If you feel dizzy while taking **Brilinta**, be careful while driving or using machines

How to take Brilinta

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

How much to take
The dose of **Brilinta** you take will depend on your condition. Your doctor will tell you the correct dose to use.
If you had a recent heart attack or unstable angina (angina or chest pain that is not well controlled). The starting dose is two tablets at the same time (loading dose of 180 mg). This dose will usually be given to you in the hospital. After this starting dose, the usual dose is one tablet of 90 mg twice a day for 12 months unless your doctor tells you differently. After one year your doctor may continue your treatment with a lower dose of 60 mg tablet twice a day.

If you had a heart attack over a year ago, the usual dose is one 60 mg tablet twice a day. Continue taking **Brilinta** as long as your doctor tells you.

Take **Brilinta** around the same time every day (for example, one tablet in the morning and one in the evening).
Your doctor will usually also tell you to take low dose aspirin. This is a substance present in many medicines used to prevent blood clotting. Your doctor will tell you how much to take (usually between 75-150 mg daily).

How to take Brilinta
- You can take the tablet with or without food
- 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 have trouble swallowing
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 hospital straight away. Take the medicine pack with you. You may be at increased risk of bleeding.

If you forget to take Brilinta

- 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 stop taking Brilinta

Do not stop taking **Brilinta** without talking to your doctor. Take **Brilinta** on a regular basis and for as long as your doctor keeps prescribing it. If you stop taking **Brilinta**, it may increase your chances of having another heart attack or dying from a disease related to your heart or blood vessels. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side Effects

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

Brilinta affects blood clotting, so most side effects are related to bleeding. Bleeding may occur in any part of the body. Some bleeding is common (like bruising and nose bleeds). Severe bleeding is uncommon, but can be life-threatening.

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 1 to 10 in 1000 people).

- **Signs of bleeding such as**:
  - bleeding that is severe or that you cannot control
  - unexpected bleeding or bleeding that lasts a long time
  - pink, red or brown urine
  - black stools (looks like tar) or red blood in your stools
  - visual disturbance caused by blood in your eye
  - coughing up or vomiting red blood or your vomit looks like ‘coffee grounds’
  - bleeding into joints causing painful swelling

- **Fainting.** This is common (affects 1 to 10 in 100 people)

- **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 -** this is very common (affects more than 10 in 100 people). It might be due to your heart disease or another cause, or it might be a side effect of **Brilinta**. **Brilinta** related breathlessness is generally mild and characterised as a sudden, unexpected hunger for air usually occurring at rest and may appear in the first weeks of therapy and for many people may disappear while treatment is continued. If you have asthma or COPD, this is more likely. 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.

- **Signs of irregular breathing (Central sleep apnoea and Cheyne-Stokes respiration) -** this has been reported in a small number of patients taking **Brilinta** (frequency cannot be estimated from the available data). Central sleep apnoea is associated with irregular breathing and may occur in patients with heart disease, stroke or other causes. Tell your doctor if you develop irregular breathing patterns such as speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.

Other possible side effects

Very common (may affect more than 10 in 100 people)

- An increase in the level of uric acid in the blood (as seen in tests)
- Bleeding caused by blood disorder

Common (may affect up to 1 to 10 in 100 people)

- 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 are signs of gout
- Feeling dizzy or light headed, or having blurred vision – these are signs of low blood pressure
- Bleeding after surgery or from cuts (e.g. while shaving) and wounds that is more than normal
- Bleeding from your stomach lining (ulcer)
- Bleeding gums

Uncommon (may affect up to 1 to 10 in 1000 people)

- Confusion
- Blood in your eye
- Vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding
- Bleeding from a tumour
- Blood in your ear

- Bleeding into joints and muscles causing painful swelling
- Internal bleeding, this may cause dizziness or light-headedness

Not known (frequency cannot be estimated from the available data)

- Slow and/or irregular heart rate
- 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 tell your doctor or pharmacist, but do not stop taking **Brilinta** until you have spoken to them.

How to store Brilinta

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.
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 **Brilinta** contains

- The active substance is ticagrelor. Each film-coated tablet contains 60 or 90 mg of ticagrelor.
- The other ingredients are:
  Tablet core: mannitol, calcium hydrogen phosphate dihydrate, sodium starch glycolate, hydroxypropyl-cellulose , magnesium stearate
  Tablet film coating: hypromellose , titanium dioxide , talc (90 mg only), polyethylene glycol 400, and ferric oxide yellow (90 mg only), ferric oxide black (60 mg only) ferric oxide red (60 mg only).

What Brilinta looks like and contents of the pack

60mg: Film-coated tablet (tablet): The tablets are round, biconvex, pink, film-coated marked with a “60” above “T” on one side and plain on the other.

90mg: Film-coated tablet (tablet): The tablets are round, biconvex, yellow, film-coated marked with a “90” above “T” on one side and plain on the other.

Brilinta 60 mg and 90 mg are available in calendar blisters (with sun/moon symbols) in cartons of 14 and 56 tablets.

Marketed by

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