**Patient Medication Information**

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

Pr **BRILINTA®**
**ticagrelor tablets**

This Patient Medication Information is written for the person who will be taking **BRILINTA®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BRILINTA**, talk to a healthcare professional.

**What BRILINTA is used for:**
BRILINTA 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:
- stroke
- heart attack
- heart or blood vessel problems.

BRILINTA is given to patients who:
- have had a heart attack or angina (chest pain)
- have had a heart attack over a year ago and are at high risk of having a heart attack or stroke
- have coronary artery disease (buildup of plaque in the arteries), type 2 diabetes, no history of a heart attack or stroke, and have previously had a procedure to open a blocked or narrowed heart blood vessel (percutaneous coronary intervention or PCI). This may have included placement of a small tube (stent) to keep the blocked or narrowed blood vessel open. These patients also have a high risk of having a heart attack or stroke.

**How BRILINTA works:**
BRILINTA belongs to a group of medicines called antiplatelet agents. Platelets are very small fragments in the blood that clump together during blood clotting.
BRILINTA helps prevent this clumping and reduces the risk of blood clots forming.

**The ingredients in BRILINTA are:**
Medicinal ingredient: ticagrelor
Non-medicinal ingredients: dibasic calcium phosphate, ferric oxide black (60 mg coating only), ferric oxide red (60 mg coating only), ferric oxide yellow (90 mg coating only), hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, polyethylene glycol 400, sodium starch glycolate, talc (90 mg coating only) and titanium dioxide.

**BRILINTA comes in the following dosage form:**
Tablets: 60 mg and 90 mg.

**Do not use BRILINTA if:**
- you are allergic to ticagrelor or any of the ingredients in BRILINTA.

- 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.
- you have a history of bleeding inside your skull or brain.
- you have liver problems.
- you are taking the following medicines:
  - ketoconazole, a medicine used to treat fungal infections,
  - clarithromycin, a medicine used to treat bacterial infections,
  - nefazodone, a medicine used to treat depression,
  - ritonavir or atazanavir, medicines used to treat HIV/AIDS.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BRILINTA. Talk about any health conditions or problems you may have, including if you:**
- have an increased risk of bleeding because of:
  - a recent serious injury
  - your daily activities put you at high risk of having a serious injury
  - recent surgery (including dental procedures)
  - recent bleeding from your stomach or gut (such as a stomach ulcer or colon 'polyps')
  - a bleeding disorder
- have an increased risk of bleeding because you take any of the following:
  - blood thinners such as warfarin
  - medicines that help dissolve blood clots such as streptokinase and alteplase
  - non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, celecoxib and naproxen
  - high dose acetylsalicylic acid (aspirin)
- are having surgery (including dental procedures) at any time while taking BRILINTA.
- had a stroke in the past.
- have a history of slow heartbeat, are taking medicines that slow down your heartbeat or have a condition that puts you at risk of having slow heartbeat episodes.
- have a history of asthma or other breathing problems.
- have a history of gout.
- have been told by a healthcare professional that you have high levels of uric acid in your blood.
- have kidney problems.

**Other warnings you should know about:**
**Do not stop taking BRILINTA without first talking to your healthcare professional. If you stop taking BRILINTA, blood clots may form and cause a stroke, heart attack, or other serious complications. This can lead to severe disability or even death.**

**BRILINTA may cause serious side effects, including:**
- **Increased levels of uric acid in the blood:** This can lead to a disease called gout that causes painful joints. Tell your healthcare professional **right away** if you experience red, swollen, hot or painful joints.
- **Bradyarrhythmia** (slower than normal heart rate related to problems with the control of the heart rhythm): This may happen shortly after taking BRILINTA. Your healthcare professional will closely monitor your heart rate during the first few weeks of treatment. Tell your healthcare professional **right away** if you experience a slow heart rate.

- **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 BRILINTA. This condition can cause serious complications or even death. Tell your healthcare professional **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
- **Dyspnea** (shortness of breath): This includes shortness of breath when you are at rest, active and during sleep. It usually stops as you continue taking BRILINTA. Tell your healthcare professional **right away** if you experience shortness of breath, especially if it gets worse or does not seem to go away.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

**Irregular breathing:** The following side effects were reported in a small number of patients while taking BRILINTA (frequency cannot be estimated from the available data):
- **Central sleep apnea** (disorder in which your breathing repeatedly stops and starts during sleep, and may occur in patients with heart disease, stroke or other causes)
- **Cheyne-Stokes respiration** (a rare abnormal breathing pattern that involves a period of fast, shallow breathing followed by slow heavier breathing and moments without any breath at all)

Tell your healthcare professional if you develop any of the irregular breathing side effects above. Your healthcare professional will decide if you need further evaluation.

**Surgery:**
- If you should see another healthcare professional or a dentist, you should inform them that you are taking BRILINTA.
- Tell your healthcare professional if you are going to have any surgeries, including dental procedures, while taking BRILINTA. There is an increased risk of bleeding if you take BRILINTA during these procedures. It can be life threatening.
- Your healthcare professional may ask you to stop taking BRILINTA before the surgery, and to resume taking BRILINTA after the procedure. It is important that you take BRILINTA before and after the procedure exactly at the times the healthcare professional has instructed.

**Driving and using machines:** BRILINTA can cause dizziness, confusion, vertigo and fainting. You should not drive or use machines until you know how BRILINTA affects you.

**Pregnancy:**
- It is not known if BRILINTA can cause harm to your baby during pregnancy. Therefore, BRILINTA should not be used while you are pregnant.
- Your healthcare professional may recommend that you use a highly effective birth control method while taking BRILINTA.
- Talk to your healthcare professional **right away** if you discover that you are pregnant while taking BRILINTA.

**Breastfeeding:** It is not known if BRILINTA can pass into breast milk. Therefore, BRILINTA should not be used during breastfeeding. Talk to your healthcare professional about ways to feed your baby if you were planning to breastfeed while taking BRILINTA.
**Check-ups and testing:** If you have coronary artery disease and type 2 diabetes, your healthcare professional will regularly monitor you to make sure BRILINTA is right for you. Your healthcare professional will discuss any risks and ways to prevent possible side effects while you are taking BRILINTA.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Serious drug interactions:

Serious drug interactions with BRILINTA include:
- ketoconazole, a medicine used to treat fungal infections,
- clarithromycin, a medicine used to treat bacterial infections,
- nefazodone, a medicine used to treat depression,
- ritonavir or atazanavir, medicines used to treat HIV/AIDS.

Taking BRILINTA with these medicines may cause serious drug interactions. Ask your healthcare professional if you are unsure.

**The following may also interact with BRILINTA:**
- blood thinners such as warfarin
- medicines that help dissolve blood clots such as streptokinase and alteplase
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, celecoxib and naproxen
- high dose (greater than 150 mg daily) acetylsalicylic acid (aspirin)
- rifampin, a medicine used to treat bacterial infections
- medicines used to prevent epilepsy or seizures such as carbamazepine, phenytoin, or phenobarbital
- dexamethasone, a medicine used to relieve inflammation and treat other conditions
- cyclosporine, a medicine used to suppress your immune system
- rosuvastatin, simvastatin, or lovastatin, medicines used to treat high blood cholesterol
- digoxin, a medicine used to treat various heart conditions
- morphine, a medicine used to relieve pain

Know the medicines you take. Ask your healthcare professional if you are not sure whether your medicine is one of the medicines listed above. Keep a list of them to show your healthcare professional or pharmacist when you get a new medicine.

While you are on BRILINTA it is important that you do not take any medicine other than that prescribed by your healthcare professional.

**How to take BRILINTA:**
- Take BRILINTA with or without food.
- Take BRILINTA exactly as your healthcare professional tells you.
- Swallow the BRILINTA tablet whole with some water.
- Take one in the morning and one in the evening at around the same time every day.
- Your healthcare professional will usually also tell you to take low dose acetylsalicylic acid (aspirin) (between 75 mg and 150 mg) once a day.

- Your healthcare professional will tell you how long you should take BRILINTA. Do not stop taking BRILINTA without first talking to your healthcare professional.

**If you have trouble swallowing the tablet(s),** follow the steps below to crush the BRILINTA tablet(s). This will help make sure that all of the crushed tablet(s) will be transferred to the drinking glass.
- use a mortar and pestle or a similar device to crush the tablet(s)
- add a small amount of water (100 mL) to the mortar and pestle/device and stir for 1 minute
- transfer the water and crushed tablet mixture to a drinking glass
- add more water (100 mL) to the mortar and pestle/device and stir for 30 seconds
- transfer the water and crushed tablet mixture to the same drinking glass
- stir the contents of the drinking glass and drink it right away

**How to use the blister (4x15 tablets) pack:**
BRILINTA comes in a blister pack with the time of day printed on the back of the blister (to help you keep track of your doses).

There are 15 tablets in each blister: 14 are labelled with the time of day (AM or PM), one is labelled as “Start Here AM/PM”. All 15 tablets are exactly the same. Use the following dosing instructions:

First dose for each blister pack:
- Start with the tablet that is labelled **“Start Here AM/PM”**,

Second dose (one tablet) from the blister pack:
- Take your second tablet (about 12 hours later) that matches the time of day (AM or PM),

Next doses from the blister pack:
- Continue to take one tablet alternating morning (AM) and evening (PM), until they are all finished.

**Usual dose:**
**Adults – 90 mg**
If you had a recent heart attack or angina (chest pain), a healthcare professional will give you 180 mg (two 90 mg tablets) of BRILINTA for your first dose. After this first dose, the usual dose is one 90 mg tablet twice a day.

After one year your healthcare professional may continue your treatment with a lower dose of BRILINTA.

**Adults – 60 mg**
The usual dose is one 60 mg tablet twice a day if you:
- had a heart attack over a year ago, or
- have coronary heart disease, type 2 diabetes, no previous history of a heart attack or stroke, and have had a procedure to open a blocked or narrowed heart blood vessel (PCI).

**Overdose:**
Symptoms of an overdose include:
- excessive bleeding
- shortness of breath
- pauses in heartbeat

If you think you, or a person you are caring for, have taken too much BRILINTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed dose:**
If you forget or miss a dose of BRILINTA, skip the missed dose and take the next dose as scheduled. **Do not double the dose to make up for the missed dose.**

**Possible side effects from using BRILINTA:**
These are not all the possible side effects you may have when taking BRILINTA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of BRILINTA are:
- Headache
- Feeling dizzy or like the room is spinning
- Abdominal pain, constipation, diarrhea or indigestion (heartburn)
- Nausea or vomiting
- Itching
- A tingling feeling
- Inflamed stomach lining
- Fatigue, muscle weakness
- Anxiety
- Sore throat or runny nose
- Cough
- Feeling dizzy or lightheaded, or having blurred vision (signs of low blood pressure)
- Bleeding gums

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 the **Serious side effects and what to do about them** table below).

BRILINTA can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**Serious side effects and what to do about them**

| Frequency/Side Effect/Symptom | Talk to your healthcare professional | | Stop taking this drug and get immediate medical help |
|---|---|---|---|
| | Only if severe | In all cases | |
| **Very common** | | | |
| Bleeding caused by blood disorder | | ✓ | |
| **Dyspnea** (shortness of breath) | | ✓ | |
| **Increased levels of uric acid in the blood:** possible red, swollen, hot and painful joint (signs of gout) | | ✓ | |
| **Common** | | | |
| **Bleeding:** blood in your urine (pink, red or brown urine) or stools (red or black | | ✓ | |

| Frequency/Side Effect/Symptom | Talk to your healthcare professional | | Stop taking this drug and get immediate medical help |
|---|---|---|---|
| | Only if severe | In all cases | |
| stools – looks like tar), vomiting blood, coughing up blood, nosebleed, bruising or bleeding into the skin, bleeding more than normal after surgery or cuts or wounds, bleeding that is severe or that lasts a long time | | | |
| Chest pain | | ✓ | |
| **Heart problems:** rapid, slow or irregular heartbeat or increased fatigue, swelling of legs and feet and shortness of breath | | ✓ | |
| **Signs of a stroke including:**<br>• sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body.<br>• sudden confusion, difficulty speaking or understanding others.<br>• sudden difficulty in walking or loss of balance or coordination.<br>• suddenly feeling dizzy or sudden severe headache with no known cause. | | | ✓ |
| Sleeplessness | | ✓ | |
| Swelling of your legs or ankles | | ✓ | |
| **Syncope** (fainting): temporary loss of consciousness due to sudden drop in blood flow to the brain | | ✓ | |
| **Uncommon** | | | |
| **Anemia** (decreased number of red blood cells): shortness of breath, paleness, weakness | | ✓ | |
| **Bleeding:** blood in your eye, ear or tumour, heavier vaginal bleeding or bleeding at different times than normal menstrual bleeding, bleeding into joints and muscles causing painful swelling, internal bleeding that may cause dizziness or light-headedness | | ✓ | |
| Confusion | | ✓ | |
| **Intracranial hemorrhage** (bleeding in the skull or brain): sudden, severe headache, confusion, nausea and vomiting, seizures, loss of consciousness | | | ✓ |

| Frequency/Side Effect/Symptom | Talk to your healthcare professional | | Stop taking this drug and get immediate medical help |
|---|---|---|---|
| | Only if severe | In all cases | |
| **Kidney stones:** pain when urinating, severe pain in the side and back, below the ribs | | ✓ | |
| **Lung fibrosis** (scarring of the lungs): shortness of breath, dry cough, fatigue, aching muscles and joints, unexplained weight loss | | ✓ | |
| **Pulmonary hypertension** (high blood pressure in the lungs): shortness of breath, dizziness, fatigue, racing pulse | | ✓ | |
| **Unknown** | | | |
| **Allergic reaction:** rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing | | | ✓ |
| **Bradyarrhythmia** (slower than normal heart rate related to problems with the control of heart rhythm): fainting or near-fainting, light-headedness, weakness, fatigue, shortness of breath, confusion or memory problems | | ✓ | |
| Rash | | ✓ | |
| **Thrombotic Thrombocytopenic Purpura (TTP)** (a rare disorder that causes blood clots to form in small blood vessels throughout the body): 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 | | ✓ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

- Store your BRILINTA tablets between 2-30°C.
- Keep BRILINTA and all medicines out of the reach and sight of children.
- The expiry date of this medicine is printed on the package label. Do not use the medicine after this date.

**If you want more information about BRILINTA:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.astrazeneca.ca or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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