PART III:
CONSUMER INFORMATION

Pr BRILINTA®

ticagrelor tablets

This leaflet is part III of a three-part "Product Monograph" published when BRILINTA® was approved for sale in Canada and is designed specifically for Consumers/Care givers. This leaflet is a summary and will not tell you everything about BRILINTA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

BRILINTA is used in combination with low dose acetylsalicylic acid (aspirin) to reduce the risk of:

- having a stroke
- having another heart attack
- dying from a disease related to the heart or blood vessels.

BRILINTA 90 mg is given to patients who have had a heart attack or angina (chest pain).

BRILINTA 60 mg is given to patients who had a heart attack over a year ago.

What it does:

BRILINTA contains a medicine called ticagrelor. This belongs to a group of medicines called antiplatelet agents.

Platelets are small fragments circulating in your blood. Platelets help stop bleeding. When a blood vessel is damaged, they clump together to help form a blood clot, which stops 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 or stroke.
- the clot can partly block the blood vessels to the heart - this can cause chest pain which comes and goes (angina).

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

When it should not be used:

- You are allergic (hypersensitive) to ticagrelor or any of the ingredients of BRILINTA.
- You have active bleeding such as bleeding in your stomach or gut from an ulcer or bleeding in your brain.
- You have moderate to severe liver disease.
- You have had a stroke caused by bleeding in the brain.
- You are taking medication known as strong CYP3A4 inhibitors such as ketoconazole, clarithromycin, nefazodone, ritonavir and atazanavir.

What the medicinal ingredient is:

Ticagrelor

What the nonmedicinal ingredients are:

Dibasic calcium phosphate, ferric oxide black (60 mg coating), ferric oxide red (60 mg coating), ferric oxide yellow (90 mg coating), hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, polyethylene glycol 400, sodium starch glycolate, talc (90 mg coating) and titanium dioxide.

What dosage forms it comes in:

Film-coated tablets, 60 mg and 90 mg.

WARNINGS AND PRECAUTIONS

BEFORE you take BRILINTA talk to your doctor, pharmacist or dentist 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')
  - a blood clotting disorder
- You have an increased risk of bleeding because you take any of the following:
  - blood thinners such as warfarin
  - fibrinolytic drugs that help dissolve blood clots
  - nonsteroidal anti-inflammatory drugs such as ibuprofen, and naproxen
  - high dose acetylsalicylic acid (aspirin)
  - drugs such as ketoconazole, clarithromycin, nefazodone, ritonavir, atazanavir
- You are due to have surgery (including dental procedures) at any time while taking BRILINTA. Your doctor may want you to stop taking BRILINTA for a short time to reduce the risk of bleeding.
- You had a stroke in the past.
- You are taking drugs to reduce the heart rate or if you have a condition that puts you at risk of having episodes of slow heart rate.
- You have a history of asthma or other breathing problems.
- You have a history of gouty arthritis or increased plasma uric acid levels.
- You are less than 18 years old.
- You are pregnant or plan to become pregnant. If you are of child-bearing age, use appropriate birth control to avoid pregnancy.
- You are breast-feeding.

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

If you should see another doctor or a dentist, you should inform them that you are using BRILINTA.

Driving or using machines
If you feel dizzy or confusion while taking BRILINTA, be careful when driving or using machines.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. 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:
- '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 to prevent or treat blood clots.
- Non-steroidal anti-inflammatory drugs (NSAIDs).
- Ketoconazole, clarithromycin, nefazodone, ritonavir and atazanavir.
- High dose (greater than150 mg daily) acetylsalicylic acid (aspirin).
- More than 40 mg daily of either simvastatin or lovastatin.
- Digoxin.
- Cyclosporine.
- Rifampin, phenytoin, carbamazepine, phenobarbital and dexamethasone.

Keep a list of the medicines you take and show it to your doctor and pharmacist when you get a new medicine.

PROPER USE OF THIS MEDICATION

For BRILINTA 60 mg and 90 mg:
- Take BRILINTA with or without food.
- 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 doctor will also tell you to take low dose aspirin (acetylsalicylic acid) (between 75 mg and 150 mg) once a day.
- Your doctor will tell you how long you should take BRILINTA. Do not stop taking BRILINTA without first talking to your doctor.

Usual dose:
Adults – 90 mg
If you had a recent heart attack or unstable angina, the usual dose is one 90 mg tablet twice a day.

When you arrived at the hospital, you received 180 mg (two 90 mg tablets) of BRILINTA. This is different than the **Usual 90 mg dose** that is prescribed to you. Always follow your doctor's instructions.

After one year your doctor may continue your treatment with a lower dose of one 60 mg tablet twice a day.

Adults – 60 mg
If you had a heart attack over a year ago, the usual dose is one tablet of 60 mg twice a day.

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.

Steps
- 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.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take more BRILINTA tablets than you should, you may be at increased risk of bleeding.

Missed dose:

If you forget to take your scheduled dose of BRILINTA, take your next dose at its scheduled time. Do not take a double dose (two tablets at the same time) to make up for the forgotten tablet.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, BRILINTA may have unwanted effects on some people.

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.

The most common side effects of BRILINTA are:

- Headache
- Feeling dizzy or like the room is spinning
- Abdominal pain, constipation, diarrhea or indigestion
- Nausea or vomiting
- Itching
- Confusion
- A tingling feeling
- Inflamed stomach lining
- Fatigue, muscle weakness
- Anxiety
- Cough
- Severe pain and swelling in your joints (signs of gout)
- Feeling dizzy or lightheaded, or having blurred vision (signs of low blood pressure)
- Bleeding from your stomach lining (ulcer)
- Bleeding gums

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Very Common			
Feeling short of breath		X	
An increase in the level of uric acid in the blood (possible red, swollen, hot and painful joint)		X	
Bleeding caused by blood disorder		X	
Common			
Bleeding: blood in your urine (pink, red or brown urine) or stools (red or black 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		X	
Swelling of your legs or ankles		X	
Heart problems: rapid, slow or irregular heartbeat or increased fatigue, swelling of legs and feet and shortness of breath		X	
Chest pain		X	
Fainting (syncope): temporary loss of consciousness due to sudden drop in blood flow to the brain		X	
Signs of a stroke including: •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 coordination. •suddenly feeling dizzy or sudden severe headache with no known cause.			X
Sleeplessness		X	
Uncommon			
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		X	
Confusion		X	
Anemia: shortness of breath, paleness, weakness		X	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
	Only if severe	In all cases	
Kidney stones: pain when urinating, severe pain in the side and back, below the ribs		X	
Lung fibrosis: shortness of breath, dry cough, fatigue, aching muscles and joints, unexplained weight loss		X	
High blood pressure in the lungs: shortness of breath, dizziness, fatigue, racing pulse		X	
Unknown			
Allergic Reaction: rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			X
Rash		X	

This is not a complete list of side effects. For any unexpected effects while taking BRILINTA, contact your doctor or pharmacist.

HOW TO STORE IT

Keep BRILINTA and all medicines out of the reach and sight of children.

Store your BRILINTA tablets between 2-30°C.

The expiry date of this medicine is printed on the package label. Do not use the medicine after this date.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

This document plus the full Product Monograph, prepared for health professionals, can be found at: www.astrazeneca.ca or by contacting AstraZeneca Canada Inc., at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

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