

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:

You have been prescribed BRILINTA because you have had a heart attack or angina (chest pain). BRILINTA taken with low dose acetylsalicylic acid (aspirin) reduces the risk of:

- having a stroke
- having another heart attack
- dying from cardiovascular disease.

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 (see What the nonmedicinal ingredients are).
- You have problems with bleeding, such as bleeding in your stomach or gut from an ulcer.
- 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 yellow, hydroxypropyl cellulose, hypromellose, magnesium stearate, mannitol, polyethylene glycol 400, sodium starch glycolate, talc and titanium dioxide.

What dosage forms it comes in:

Film-coated tablets, 90 mg.

WARNINGS AND PRECAUTIONS

BEFORE you take BRILINTA talk to your doctor, pharmacist or dentist if:

- You are taking or planning on taking any other medications (prescription and non-prescription) as certain medications can seriously affect the way other medications work (see INTERACTIONS WITH THIS MEDICATION).
- 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')
- 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 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 gouty arthritis or increased plasma uric acid level.
- You are less than 18 years old.
- You are pregnant or plan to become pregnant.
- 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.

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 than 150 mg daily) acetylsalicylic acid (aspirin).
- Digoxin.
- Rifampin, dexamethasone, phenytoin, carbamazepine and phenobarbital.

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

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: The usual dose is one tablet twice a day, 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.

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

BRILINTA is not recommended for patients under 18 years of age.

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.

Do not take a double dose (two tablets at the same time) even if you miss a dose.

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.

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

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	
Common	Bleeding such as blood in your urine or stools (black stools)		X	
	Nosebleed		X	
	Swelling of your legs or ankles		X	
	Bruising		X	
	Rash		X	
	Arrhythmia (rapid, slow or irregular heartbeat)		X	
	Chest pain		X	
	Cardiac failure (increased fatigue, swelling of legs and feet and shortness of breath)		X	
Bleeding after surgery		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	
Uncommon	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 co-ordination. •Suddenly feeling dizzy or sudden severe headache with no known cause.		X	X
	Blood in your eye		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 0701C
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

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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