Indication and clinical use:

BRILINTA (ticagrelor), co-administered with acetylsalicylic acid (ASA), is indicated for the secondary prevention of atherothrombotic events in patients with Acute Coronary Syndromes (ACS) (unstable angina [UA], non-ST elevation myocardial infarction [NSTEMI] or ST elevation myocardial infarction [STEMI]) who are to be managed medically, and those who are to be managed with percutaneous coronary intervention (PCI) (with or without stent) and/or coronary artery bypass graft (CABG). Based on a relationship observed in PLATO between maintenance ASA dose and relative efficacy of BRILINTA compared to clopidogrel BRILINTA is recommended to be co-administered with low maintenance dose ASA (75-150 mg daily). The safety and efficacy of BRILINTA in pediatric patients below the age of 18 have not been established. Therefore, BRILINTA is not recommended in this population.

Contraindications:

- Patients with active pathological bleeding (e.g., peptic ulcer or intracranial hemorrhage)
- Patients with a history of intracranial hemorrhage
- Patients with moderate to severe hepatic impairment
- Patients who are also taking strong CYP3A4 inhibitors

Most serious warnings and precautions: Bleeding risk: BRILINTA should be used with caution in patients with a propensity to bleed (e.g., due to recent trauma, recent surgery, active or recent gastrointestinal bleeding, or moderate hepatic impairment) and in patients requiring oral anticoagulants (e.g., warfarin) and/or fibrinolytics agents (within 24 hours of BRILINTA dosing). Caution should also be used in patients with concomitant administration of medicinal products that may increase the risk of bleeding (e.g., non-steroidal anti-inflammatory drugs [NSAIDs]).

Maintenance dose ASA: Co-administration of BRILINTA and high maintenance dose ASA (>150 mg daily) is not recommended.

Other relevant warnings and precautions:

- · Cardiac events in discontinued patients
- Bradvcardic events
- · Hypersensitivity, including angioedema
- Dizziness and confusion
- · Discontinuation prior to surgery
- Dyspnea
- Pregnant or nursing women
- Possible increase in creatinine levels
- · Uric acid increase

For more information:

Consult the Product Monograph at azinfo.ca/ brilinta/pm274 for important information regarding adverse reactions, drug interactions and dosing information not discussed in this piece. The Product Monograph is also available by calling AstraZeneca Canada at 1-800-668-6000.

Reference: ${\sf BRILINTA}^{\otimes}$ Product Monograph. AstraZeneca Canada Inc. September 9, 2013.





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CMAJ encourages authors of any study involving human participants to show that their study was judged as ethical before the study was started.

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