

**PACKAGE LEAFLET: INFORMATION FOR THE USER****BRILINTA 90 mg film-coated tablets**

ticagrelor

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

**In this leaflet:**

1. What BRILINTA is and what it is used for.
2. Before you take BRILINTA.
3. How to take BRILINTA.
4. Possible side effects.
5. How to store BRILINTA.
6. Further information.

**1. WHAT BRILINTA IS AND WHAT IT IS USED FOR****What BRILINTA is**

BRILINTA contains the active substance called ticagrelor. This belongs to a group of medicines called anti-platelet medicines.

**How BRILINTA works**

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 stroke, 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.

**What BRILINTA is used for**

BRILINTA 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 you having another heart attack or a stroke or of dying from a disease related to your heart or blood vessels.

**2. BEFORE YOU TAKE BRILINTA****Do not take BRILINTA if:**

- You are allergic (hypersensitive) to ticagrelor or any of the other ingredients of BRILINTA (listed in Section 6: Further information).
- You are bleeding now or have bled recently inside your body, such as bleeding in your stomach or gut from an ulcer.
- You have moderate to 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').

- 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 7 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

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:

- 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), dexamethasone (used to treat inflammatory and auto immune conditions), digoxin (used to treat heart failure), cyclosporin (used to lessen your body's defenses), 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.
- 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).

Also tell your doctor that because you are taking BRILINTA, you may have an increased risk of bleeding if your doctor gives you fibrinolytics, often called 'clot dissolvers', such as streptokinase or alteplase.

### 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.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

### Driving and using machines

BRILINTA is not likely to affect your ability to drive or use machines.

## 3. HOW TO TAKE BRILINTA

Always take BRILINTA exactly as your doctor has told you. You should talk with your doctor or pharmacist if you are not sure.

### How much to take

- 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 up to 12 months unless your doctor tells you differently. Take BRILINTA around the same time everyday (for example, one tablet in the morning and one in the evening).

Your doctor will usually also tell you to take acetylsalicylic acid. 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 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 stroke 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.

## **4. POSSIBLE SIDE EFFECTS**

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

The frequency of possible side effects listed below is defined using the following convention:

common (affects 1 to 10 users in 100); uncommon (affects 1 to 10 users in 1,000); rare (affects 1 to 10 users in 10,000).

**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.

- **Bleeding** – some bleeding is common. However, severe bleeding is uncommon, but can be life threatening. Bleeding of many different kinds can be increased, for example:
  - Nosebleed (common).
  - Blood in your urine (uncommon).
  - Black stools or blood in your stools (common).
  - Blood in your eye (uncommon).
  - Coughing up or bringing up blood (uncommon).
  - Vaginal bleeding that is heavier, or happens at different times, to your normal period (menstrual) bleeding (uncommon).
  - Bleeding after surgery or from cuts and wounds that is more than normal (common)
  - Bleeding from your stomach lining (ulcer) (uncommon).
  - Bleeding gums (uncommon).
  - Blood in your ear (rare).
  - Internal bleeding (rare).
  - Bleeding into joints causing painful swelling (rare).

**Discuss with your doctor if you notice any of the following:**

- **Feeling short of breath** - this is common. It might be due to your heart disease or another cause, or it might be a side effect of BRILINTA. 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

tell your doctor. Your doctor will decide if it needs treatment or further investigations.

### **Other possible side effects**

#### **Common (affects 1 to 10 users in 100)**

- Bruising.

#### **Uncommon (affects 1 to 10 users in 1,000)**

- Headache.
- Feeling dizzy or like the room is spinning.
- Abdominal pain.
- Diarrhoea or indigestion.
- Feeling or being sick.
- Rash.
- Itching.
- Inflamed stomach (gastritis).

#### **Rare (affects 1 to 10 users in 10,000)**

- Constipation.
- A tingling feeling.
- Confusion.

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.

## **5. 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.

## **6. FURTHER INFORMATION**

### **What BRILINTA contains**

- The active substance is ticagrelor. Each film-coated tablet contains 90 mg of ticagrelor.
- The other ingredients are:  
*Tablet core:* mannitol (E421), dibasic calcium phosphate, sodium starch glycolate, hydroxypropyl-cellulose (E463), magnesium stearate (E470b).  
*Tablet film coating:* hypromellose (E464), titanium dioxide (E171), talc, polyethylene-glycol 400, and ferric oxide yellow (E172).

### **What BRILINTA looks like and contents of the pack**

Film-coated tablet (tablet): The tablets are round, biconvex, yellow, film-coated marked with a "90" above "T" on one side.

BRILINTA is available in:

- standard blisters (with sun/moon symbols) in cartons of 60 and 180 tablets.
- calendar blisters (with sun/moon symbols) in cartons of 14, 56 and 168 tablets.
- perforated blisters in a carton of 100x1 tablets.

Not all pack sizes may be marketed.

### **Manufacturer**

AstraZeneca AB  
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Södertälje  
Sweden

### **Date of revision of text**

December 2010

CV.000-627-494.2.0

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