PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Brilinta® 90 mg

Film-coated Tablets

Composition:

Each tablet contains:

Ticagrelor 90 mg

Brilinta® 60 mg

Film-coated Tablets

Composition:

Each tablet contains:

Ticagrelor 60 mg

For inactive ingredients, please see section 2 – "Important information regarding some of the ingerdients of the medicine" and section 6 – "Further information".

Read this leaflet carefully in its entirety before using this medicine.

Keep this leaflet; you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

Brilinta is intended for adults over the age of 18 years.

If any of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, please contact the doctor immediately.

1. WHAT IS THE MEDICINE INTENDED FOR?

Brilinta 90 mg:

Brilinta 90 mg, co-administered with acetylsalicylic acid (aspirin), is intended for use in adults only, for reducing the risk of cardiovascular events (stroke, myocardial infarction, death) in patients after myocardial infarction or after unstable angina pectoris. The use of Brilinta 90 mg is limited to one year only.

Brilinta 60 mg:

Brilinta 60 mg, co-administered with acetylsalicylic acid (aspirin), is intended for use in adults only, for reducing the risk of cardiovascular events (stroke, myocardial infarction, death) in patients who had a myocardial infarction one year ago or more. The use of Brilinta 60 mg is limited to two years only as a continuation of Brilinta 90 mg treatment or another anticoagulant.

Therapeutic group:

Inhibits platelet activity by reversible and competitive inhibition of the platelets.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you have a known sensitivity to ticagrelor or to any of the other ingerdients of the medicine (please see section 6 'Further Information').
- you are currently suffering from bleeding.
- you are suffering from a severe liver disease.
- you are taking any of the following medicines: ketoconazole (used to treat fungal infections), clarithromycin (for treatment of bacterial infections), nefazodone (antidepressant), ritonavir and atazanavir (for treatment of HIV infections and AIDS).
- if you had a stroke caused by intracerebral bleeding.

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 this medicine.

Special warnings regarding use of Brilinta

Before treatment with Brilinta, inform the doctor if:

- you are at increased risk of bleeding due to:
    - Recent severe injury or surgery (including dental work, ask your dentist about this)
    - Recent bleeding in the stomach or intestine (such as a stomach ulcer or colon ‘polyps’)
    - Disease/condition that affects blood clotting.
- you are due to undergo surgery (including dental work) – during the course of treatment with this medicine, the doctor may instruct you to stop taking Brilinta 5 days before the planned surgery, to reduce the risk of bleeding.
- you are suffering from a slow heart rate (below 60 beats per minute) and you do not have a pacemaker.
- you are suffering from asthma or a lung disease or difficulty breathing.
- you develop irregular breathing patterns such as speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.
- you have had liver problems or have suffered in the past from a disease which may affect your liver.
- you have had a blood test that showed that you are suffering from high levels of uric acid in the blood.

If one of the above applies to you (or if you are not sure), talk to your doctor or pharmacist before taking the medicine.

If you are taking both Brilinta and heparin:

- Your doctor may require a sample of your blood for diagnostic tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both Brilinta and heparin, as Brilinta may affect the diagnostic test.

Drug interactions

If you are taking, or if you have recently taken, other medicines including non-prescription medicines, vitamins, nutritional supplements and herbal remedies, tell the doctor or pharmacist. This is because Brilinta may affect the way certain medicines work, and certain medicines may affect the way Brilinta works.
Inform the doctor or pharmacist if you are taking:

- rosuvastatin (a medicine to treat high cholesterol)
- simvastatin or lovastatin (medicines for treatment of high cholesterol) at doses higher than 40 mg per day
- rifampicin (antibiotic)
- phenytoin, carbamazepine and phenobarbital (for treatment of convulsions)
- digoxin (for treatment of heart failure)
- cyclosporine (immunosuppressant)
- quinidine and diltiazem (for treatment of heart rhythm disorders)
- beta blockers and verapamil (for treatment of hypertension)
- morphine and other opioids (used to treat severe pain)

Especially if you are taking medicines from the following groups that may increase the risk of bleeding:

- Oral anticoagulants (blood thinners) including warfarin.
- Non-steroidal anti-inflammatory drugs (NSAIDs), often taken as pain killers, such as ibuprofen and naproxen.
- Antidepressants from the SSRIs group, such as paroxetine, sertraline and citalopram.
- Ketoconazole (for treatment of fungal infections); Clarithromycin (for treatment of bacterial infections); Nefazodone (for treatment of depression); Ritonavir and atazanavir (for treatment of HIV infections and AIDS); Cisapride (for treatment of heartburn); Ergotamines (for treatment of migraine and headaches).

Also tell your doctor if you are taking fibrinolytics (clot dissolvers) such as streptokinase or alteplase because of the increased risk of bleeding.

Use of Brilinta and food

The tablet can be taken with or without food.

Pregnancy and breastfeeding

- Do not use Brilinta without consulting a doctor if you are pregnant or planning to become pregnant. Women taking Brilinta must use appropriate contraceptive measures to prevent pregnancy.
- Consult a doctor before using this medicine if you are breastfeeding, your doctor will discuss with you the benefits and risks of taking Brilinta during this time.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and use of machinery

Brilinta is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking Brilinta, be careful while driving or using machines.

Important information about some of the ingredients of the medicine

Brilinta 90 mg and Brilinta 60 mg:

this medicine contains less than 1 mmol sodium (23 mg) per dose that is to say it is essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with this medicine.

The doctor will explain to you how to take the medicine (how many tablets and when to take them). The dosage and duration of treatment are determined by the doctor in accordance with the disease from which you are suffering.

The usual dosage is generally:

Brilinta 90 mg:

- The starting dosage is 2 tablets at the same time (loading dose of 180 mg). This dose is usually given in the hospital.
- After the starting dosage, the usual dosage is one 90 mg tablet, twice a day, for up to 12 months.

Brilinta 60 mg:

- The usual dose is one tablet of 60 mg, twice a day. Continue taking Brilinta 60 mg as long as your doctor tells you and up to two years. The doctor will instruct you to take a low dosage of aspirin (to prevent clotting) as a supplement to treatment with Brilinta.

  Do not discontinue taking Brilinta without instructions from the doctor.

Directions for use:

- The tablet can be taken with or without food.
- Swallow the tablet whole.
- Take the tablet at set times in the day (e.g., one tablet in the morning and one tablet in the evening). You can check when you last took a tablet of Brilinta by looking on the blister. There is a sun (tablet for the morning) and a moon (tablet for the evening).
- **Do not exceed the recommended dose.**
- If you have trouble swallowing the tablets you can crush them and mix with water as follows:
    - Crush the tablet to a fine powder
    - Pour the powder into half a glass of water
    - Stir and drink immediately
    - To make sure there is no medicine left, rinse the empty glass with another half a glass of water and drink it.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed this medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of Brilinta with you. An overdose can cause increased risk of bleeding.

If you forgot to take this medicine at the scheduled time, do not take the forgotten dose; take the next dose at the scheduled time. Do not take two doses at the same time to compensate for the missed dose.

How can you contribute to the success of the treatment?

Complete the treatment recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with the medicine without consulting the doctor. Such discontinuation may increase your risk of another heart attack, stroke or death from a disease associated with the heart or blood vessels.

Be sure to strictly follow the administration instructions and to ask the doctor if you have any uncertainty.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of this medicine, consult with your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Brilinta may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

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 nosebleeds). Severe bleeding is uncommon, but can be life threatening.

Effects that require special attention:

Refer to the doctor immediately if the following effects occur:

Bleeding into the brain or inside the skull is an uncommon side effect, and may cause signs of a stroke such as:

- Sudden numbness or weakness of the arm, leg or face, particularly on one side of the body.
- Sudden confusion, difficulty speaking or understanding others.
- Sudden difficulty walking or loss of balance or co-ordination.
- Sudden dizziness or sudden severe headache without a known reason.

Signs of bleeding such as:

- bleeding that is severe or cannot be controlled.
- unexpected bleeding or bleeding that lasts a long time.
- pink, red or brown urine.
- bloody vomit or your vomit looks like "coffee grounds".
- black or bloody stools (look like tar).
- coughing up or vomiting blood clots.

Fainting (syncope)

- a temporary loss of consciousness due to sudden drop in blood flow to the brain (common).

Signs of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) such as:

- 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.

Consult a doctor if the following effects occur:

- **Feeling short of breath - this is very common.** It might be due to your heart disease or another cause, or it might be a side effect of Brilinta. Brilinta-related breathlessness is generally mild and characterised as a sudden, unexpected hunger for air, usually occurring at rest and may appear in the first weeks of therapy and for many may disappear. If your feeling of shortness of breath gets worse with time or lasts a long time, tell your doctor who will decide if treatment or further investigation is necessary.

Other side effects:

Side effects which occur very frequently (affect more than 1 in 10 patients):

- High level of uric acid in the blood (as observed in tests).
- Bleeding caused by blood disorders.

Side effects which occur frequently (affect 1 to 10 patients in 100):

- Bruises
- Headache
- Dizziness or a feeling like the room is spinning
- Diarrhea or digestive disturbances
- Nausea
- Constipation
- Rash, stinging and itching
- Severe pain and swelling in your joints – these are signs of gout
- Feeling dizzy or light-headed, or having blurred vision – these are signs of low blood pressure
- Nosebleed
- Bleeding after surgery or from cuts (for example while shaving) and wounds more than is normal
- Bleeding from your stomach lining (ulcer)
- Bleeding gums

Side effects which occur infrequently (affect up to 1 patient in 100):

- Hypersensitivity reaction (allergic reaction) – rash, itching, swelling of the face or lips/tongue may be signs of an allergic reaction.
- Confusion
- Visual problems caused by blood in your eye
- Vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding
- Bleeding into your joints and muscles causing painful swelling
- Blood in your ear

- Internal bleeding that causes dizziness or light-headedness

Unknown side effects (frequency cannot be estimated from the available data)

- Abnormally Low heart rate (usually lower than 60 beats per minute)

If a side effect appears, if any of the side effects worsen or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il /

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not store above 30°C.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. In any case of doubt, consult the pharmacist who dispensed this medicine to you.
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

Brilinta 90 mg:

In addition to the active ingredient, the medicine also contains:
Mannitol (E421), Dibasic calcium phosphate, Sodium starch glycolate, Hydroxypropyl cellulose, Magnesium stearate, Hypromellose, Titanium dioxide (E171), Talc, Polyethylene glycol 400, Ferric oxide yellow.

What the medicine looks like – Brilinta 90 mg?

The tablet is film-coated, round, biconvex, yellow, with "90" imprinted on one side, above the letter "T".
The package contains 14, 56, 60 or 168 tablets.
Not all pack sizes may be marketed.

Brilinta 60 mg:

Mannitol (E421), Dibasic calcium phosphate, Sodium starch glycolate, Hydroxypropyl cellulose, Magnesium stearate, Hydroxypropyl methylcellulose, Titanium dioxide, Polyethylene glycol 400, Ferric oxide black, Ferric oxide red.

What the medicine looks like – Brilinta 60 mg?

The tablet is film-coated, round, biconvex, pink, with "60" imprinted on one side, above the letter "T".

The package contains 14, 56, 60, 100, 168 or 180 tablets.

Not all pack sizes may be marketed.

Manufacturer:

AstraZeneca AB,

Sodertalje, Sweden.

License holder and importer:

AstraZeneca (Israel) Ltd.,

1 Atirei Yeda St., Kfar Saba 4464301.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Brilinta 90 mg: 146-66-33358-00

Brilinta 60 mg: 156-54-34752-00

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