**Brilique 90 mg, film-coated tablets**

**What is Brilique?**Brilique contains the active substance ticagrelor. This belongs to a group of medicines called platelet aggregation inhibitors.

**What is Brilique used for?**Brilique, in combination with acetylsalicylic acid (another platelet aggregation inhibitor), is only to be used by adults. You have been given Brilique because you: had a heart attack more than one year ago.

Brilique reduces the risk of having another heart attack, stroke, or dying from a disease related to your heart or blood vessels.

**How does Brilique work?**Brilique works on cells called platelets or thrombocytes. These very small blood cells help stop bleeding by clumping together to seal small holes in blood vessels that have been damaged.

Platelets can also form clots inside a damaged blood vessel. This can be very dangerous because:

* the clot can completely block the blood supply – this can cause a heart attack (myocardial infarction) or a stroke.
* the clot can partially block blood flow to the heart – this can cause chest pain that sometimes goes away but can come back later (called unstable angina).

Brilique prevents platelets from clumping together, reducing the chances of a clot forming and blocking blood vessels.

**When should you not use this medicine or use it with extra caution?**

**When should you not use this medicine?**

* You are allergic to any of the substances in this medicine.
* You have bleeding.
* You have previously had a stroke caused by bleeding in your brain (intracranial bleeding).
* You have a severe liver disease.
* You are currently 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 and AIDS).
* If one or more of the above descriptions apply to you, you must not use Brilique. If you are unsure, please consult your doctor or pharmacist before using this medicine.

**When should you use this medicine with extra caution?**Contact your doctor or pharmacist before using this medicine if:

* You have an increased risk of bleeding because, for example, you:
* Have recently had a serious injury.
* Have recently undergone surgery (including dental surgery; please consult your dentist).
* Have a bleeding disorder.
* Have recently had a stomach or intestinal bleeding (such as a stomach ulcer or colon polyp).
* You need surgery during your treatment with Brilique (including dental surgery). This is because of the increased risk of bleeding. Your doctor may want you to stop using this medicine 7 days before the procedure.
* Your heart rate is abnormally low (usually less than 60 beats per minute), and you do not have a device to regulate your heart rate (pacemaker).
* You have asthma or other lung problems that make breathing difficult.
* You have had liver problems, or you have had a condition in the past that has affected your liver.
* You have had a blood test indicating elevated uric acid levels.
* If one or more of the above descriptions apply to you, or if you are unsure, please consult your doctor or pharmacist before using this medicine.

**Children and adolescents under 18 years of age**The use of Brilique is not recommended for children and adolescents under 18 years of age.

**Are you using any other medications?**Are you using or have you recently used any other medications or do you plan to use other medications in the near future? Please inform your doctor or pharmacist. This is important because Brilique may affect the effectiveness of some other medicines, and other medicines may have an impact on Brilique.

It is important that you inform your doctor or pharmacist if you are using any of the following medications:

* More than 40 mg of simvastatin or lovastatin per day (medications used to treat high cholesterol).
* Rifampicin (an antibiotic).
* Phenytoin, carbamazepine, and phenobarbital (used to treat seizures).
* Digoxin (used to treat heart failure).
* Ciclosporin (used to reduce your body's immune response).Quinidine and diltiazem (used to treat abnormal heart rhythms).Beta-blockers and verapamil (used to treat high blood pressure).

It is particularly important to inform your doctor or pharmacist if you are using any of the following medications because they can increase the risk of bleeding:

* Oral anticoagulants, often referred to as blood thinners; an example is warfarin.
* Non-steroidal anti-inflammatory drugs (NSAIDs), commonly used pain relievers such as ibuprofen and naproxen.
* Selective serotonin reuptake inhibitors (often abbreviated as SSRIs), a specific type of antidepressant such as paroxetine, sertraline, and citalopram.
* Other medications such as ketoconazole (used for fungal infections), clarithromycin (used for bacterial infections), nefazodone (an antidepressant), ritonavir, and atazanavir (used in the treatment of HIV and AIDS), cisapride (used for heartburn), ergot alkaloids (used for migraine and headache).
* Also, inform your doctor that you have an increased risk of bleeding due to using Brilique if your doctor gives you fibrinolytics, often referred to as "clot busters," such as streptokinase or alteplase.

**Pregnancy and breastfeeding**It is not recommended to use Brilique if you are pregnant or trying to become pregnant. Women should use appropriate contraceptives while taking Brilique.

Consult your doctor before using Brilique while breastfeeding. Your doctor will discuss the pros and cons of using Brilique during this period with you.

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Then, please contact your doctor or pharmacist before using this medicine.

**Driving and using machinery**It is unlikely that Brilique will affect your ability to drive or operate machinery. If you feel dizzy or confused while using this medicine, be cautious when driving or operating machinery.

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

**How much to take?**The starting dose is two tablets at once (an initial dose of 180 mg). You will usually receive this dose in the hospital. After the initial dose, the usual dose is one 90 mg tablet twice a day, for a period of 12 months unless your doctor tells you otherwise. Take this medicine every day at approximately the same time (e.g., one tablet in the morning and one in the evening).

**Using Brilique together with other blood-thinning medicines**Your doctor will normally also tell you to use aspirin (acetylsalicylic acid). Your doctor will tell you how much to take (usually between 75 mg and 150 mg per day).

**How to take Brilique?**You can take the tablet with or without food.

You can see on the blister when you took your last tablet. There is a sun (for the morning) and a moon (for the evening) depicted. This helps you know if you've taken your dose.

**If you have difficulty swallowing the tablet**

* If you have trouble swallowing the tablet, you can crush it and mix it with water as follows:
* Crush the tablet to obtain a fine powder.
* Mix the powder with half a glass of water.
* Stir this and drink it immediately.
* To ensure that no medication remains in the glass, rinse the empty glass with another half glass of water and drink it.

**Have you taken too much of this medicine?**If you have taken more Brilique than you should, it is important to consult your doctor immediately or go to the hospital. Take the medicine packaging with you. You may be at an increased risk of bleeding.

**Have you forgotten to take this medicine?**If you forget to take a dose, take the next dose at the usual time.

Do not take a double dose to make up for a missed dose.

**If you stop taking this medicine**Do not stop using this medicine without first talking to your doctor. Take this medicine for as long as your doctor prescribes it to you. If you stop using Brilique, you may increase the risk of a heart attack, stroke, or death from another heart or vascular disease related condition.

Do you have any other questions about using this medicine? Then, please contact your doctor or pharmacist.

**Possible side effects**

Like any medicine, this medicine can have side effects, although not everyone gets them. The following side effects can occur with this medicine.

Brilique works on blood clotting, so most side effects are related to bleeding. Bleeding can occur in any part of the body. A small amount of bleeding is common (such as bruising or a nosebleed). Severe bleeding sometimes occurs and can be life-threatening.

Go to your doctor immediately if you experience any of the following side effects – you may need urgent medical treatment:

Bleeding in the brain or bleeding inside your skull is a possible side effect that sometimes occurs and can cause signs of a stroke, such as:

* sudden numbness or weakness in your arms, legs, or face, especially if it occurs on one side of your body.
* sudden confusion, trouble speaking, or difficulty understanding others.
* sudden trouble walking or loss of balance or coordination.
* sudden dizziness or sudden severe headache without an obvious reason.
* The following signs of bleeding:
* Severe bleeding or bleeding that you cannot stop.
* Unexpected or prolonged bleeding.
* Pink, red, or brown-colored urine.
* Vomiting of red blood or vomit that looks like 'coffee grounds.'
* Red or black stools (resembling tar).
* Coughing up or vomiting blood clots.
* Fainting (syncope)
* Temporary loss of consciousness due to reduced blood flow to your brain (often).

Consult your doctor if you notice the following:

Shortness of breath – this is very common. The cause may be your heart condition or another issue, but it can also be a side effect of Brilique. When shortness of breath is related to the use of Brilique, it is typically mild and characterized by a sudden, unexpected need for air. This usually occurs during the first weeks of treatment when you are at rest and often goes away on its own. If your breathing problems worsen or last a long time, tell your doctor. Your doctor will decide whether it needs treatment or investigation.

Other possible side effects

Very common (may occur in more than 1 in 10 people):

* Elevated uric acid levels in your blood (indicated by tests).
* Bleeding due to blood disorders.
* Common (may occur in 1 to 10 out of 100 people):
* Bruising
* Headache
* Dizziness or a feeling of the room spinning
* Diarrhea or indigestion
* Feeling unwell (nausea)
* Constipation
* Rash
* Itching
* Severe pain and swelling in your joints – these are signs of gout
* Dizziness or a light-headed feeling or blurred vision – these are signs of low blood pressure
* Nosebleed.
* More than normal bleeding after surgery or injury (e.g., while shaving)
* Bleeding (stomach) ulcer
* Bleeding gums

Sometimes (may occur in 1 to 10 out of 1000 people):

* Allergic reaction. Rash, itching, or a swollen face, swollen lips/tongue can be signs of an allergic reaction.
* Confusion.
* Vision problems caused by blood in your eye.
* Vaginal bleeding that is heavier or occurs at a different time than your usual menstrual bleeding.
* Bleeding into your joints and muscles causing painful swellings.
* Blood from your ear.
* Internal bleeding, which can cause dizziness or a light-headed feeling.
* Reporting of side effects
* If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly via the
* national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

**How to store this medicine?**
Keep out of sight and reach of children. Do not use this medicine after the expiry date stated on the strip and on the box after "EXP" (abbreviation used for the expiration date). There is a month and a year indicated. The last day of that month is the expiration date. There are no special storage conditions for this medicine. Do not dispose of medicines in the wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. These measures will help protect the environment.