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EPAR summary for the public

Brilique

ticagrelor

This is a summary of the European public assessment report (EPAR) for Brilique. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Brilique.

What is Brilique?

Brilique is a medicine that contains the active substance ticagrelor. It is available as round, yellow tablets (90 mg).

What is Brilique used for?

Brilique is used together with aspirin to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) such as heart attacks or strokes. It is used in adults who have had a heart attack or have unstable angina (a type of chest pain caused by problems with the blood flow to the heart).

The medicine can only be obtained with a prescription.

How is Brilique used?

The starting dose of Brilique is two tablets taken at once, followed by a regular dose of one tablet taken twice a day. Patients should also be taking aspirin as directed by their doctor. The doctor may, for health reasons, tell them not to take aspirin. They should continue treatment for up to a year unless, the doctor asks them to stop taking the medicine.

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How does Brilique work?

The active substance in Brilique, ticagrelor, is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. When the blood clots, this is due to special cells in the blood called platelets aggregating (sticking together). Ticagrelor stops the platelets aggregating by blocking the action of a substance called ADP when it attaches to the surface of the platelets. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent a stroke or another heart attack.

How has Brilique been studied?

The effects of Brilique were first tested in experimental models before being studied in humans.

Brilique was compared with clopidogrel (another inhibitor of platelet aggregation) in a main study involving over 18,000 adults who had had a heart attack or had unstable angina. The patients also took aspirin and were treated for up to a year. The main measure of effectiveness was based on the number of patients having another heart attack, a stroke or dying from a cardiovascular disease.

What benefit has Brilique shown during the studies?

Brilique was shown to be beneficial to patients who have had a heart attack or unstable angina. In the main study, 9.3% of the patients taking Brilique had another heart attack, stroke or died from a cardiovascular disease compared with 10.9% of patients taking clopidogrel.

What is the risk associated with Brilique?

The most common side effects with Brilique (seen in between 1 and 10 patients in 100) are dyspnoea (difficulty breathing), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), bleeding in the skin or below the skin, bruising, and bleeding at the procedural site (where a blood vessel has been punctured). For the full list of all side effects reported with Brilique, see the package leaflet.

Brilique should not be used in people who may be hypersensitive (allergic) to ticagrelor or any of the other ingredients. It must not be used in patients who have moderate to severe liver disease or are currently bleeding, or in patients who have had a stroke caused by bleeding within the brain. It must also not be used in patients taking other medicines which have a strong blocking effect on one of the liver enzymes (CYP3A4). These are medicines such as ketoconazole (used to treat fungal infections), clarithromycin (an antibiotic), atazanavir and ritonavir (medicines used in HIV-positive patients) and nefazodone (used to treat depression).

Why has Brilique been approved?

The CHMP noted that the main study showed that, compared with clopidogrel, Brilique reduces the risk of heart attacks and cardiovascular deaths. However Brilique was not more effective than clopidogrel in reducing the risk of stroke.

The CHMP decided that Brilique's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Brilique

The European Commission granted a marketing authorisation valid throughout the European Union for Brilique to AstraZeneca on 03 December 2010. The marketing authorisation is valid for five years, after which it can be renewed.

The full EPAR for Brilique can be searched for on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Brilique, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2010.