26 March 2021
EMA/170569/2021
EMEA/H/C/001241/II/0047/G

Withdrawal of application to change the marketing authorisation for Brilique (ticagrelor)

AstraZeneca AB withdrew its application for the use of Brilique with aspirin (acetylsalicylic acid) to prevent problems caused by blood clots in adults with coronary artery disease and type 2 diabetes who have not previously had a heart attack and who have had a procedure to unblock the blood vessels of the heart (percutaneous coronary intervention, PCI).

The company withdrew the application on 5 March 2021.

What is Brilique and what is it used for?

Brilique is a medicine used together with aspirin to prevent problems caused by blood clots such as heart attacks or strokes (atherothrombotic events). It is used in adults with acute coronary syndrome, where blood flow in the vessels supplying the heart is blocked causing problems such as heart attack and unstable angina (a severe type of chest pain). Brilique is also used in adults who had a heart attack at least a year ago and are at a high risk of an atherothrombotic event.

Brilique has been authorised in the EU since December 2010. It contains the active substance ticagrelor and is available as tablets.

Further information on Brilique's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/brilique.

What change had the company applied for?

The company applied to extend the use of Brilique, together with aspirin, to prevent atherothrombotic events in adults with coronary artery disease and type 2 diabetes who have not previously had a heart attack and who have undergone PCI.

In coronary artery disease there is a narrowing or blockage of blood vessels supplying the heart muscle although the patient may not have any symptoms.

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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 cell fragments in the blood called platelets aggregating (sticking together). Ticagrelor stops the platelets aggregating by blocking the action of a substance called adenosine diphosphate (ADP) when it attaches to the surface of the platelets. This stops the platelets clumping together, reducing the risk of a blood clot forming and helping to prevent a stroke or heart attack.

In the prevention of atherothrombotic events in adults with type 2 diabetes and coronary artery disease with no previous heart attack, Brilique is expected to work in the same way as it does in its existing indications.

What did the company present to support its application?

The company presented the results of a study involving 19,220 patients with type 2 diabetes and coronary artery disease, who had not previously had either a stroke or heart attack. The study compared Brilique with placebo (a dummy treatment), both taken in combination with aspirin, and looked at prevention of stroke, heart attack or cardiovascular death (death due to problems in the heart or blood vessels).

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that Brilique could not have been authorised for the prevention of atherothrombotic events in adults with coronary artery disease and type 2 diabetes who have not previously had a heart attack and who have undergone PCI.

The Agency considered that the benefit seen with Brilique in the prevention of atherothrombotic events in adults with coronary artery disease and type 2 diabetes who have not previously had a heart attack was not sufficient to outweigh its risks, especially bleeding. In addition, it was not possible to determine whether the benefits would clearly outweigh the risks in patients who have undergone PCI.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the withdrawal was based on the fact that the Agency has requested further justification and data on the use of Brilique in the target population.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Brilique for the prevention of other diseases?

There are no consequences on the use of Brilique in its authorised uses.