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EPAR summary for the public

Efient

prasugrel

This is a summary of the European public assessment report (EPAR) for Efient. 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 Efient.

What is Efient?

Efient is a medicine that contains the active substance prasugrel. It is available as tablets (5 and 10 mg).

What is Efient used for?

Efient is taken together with aspirin to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) in patients with acute coronary syndrome who are undergoing percutaneous coronary intervention. Acute coronary syndrome is a group of conditions in which blood supply in the vessels supplying the heart is interrupted so heart tissue cannot work properly or dies. It includes unstable angina (a severe type of chest pain) and heart attack. Percutaneous coronary intervention is a procedure used to unblock the blood vessels supplying the heart.

The medicine can only be obtained with a prescription.

How is Efient used?

Efient treatment starts with one 60-mg dose. This is then followed by 10 mg taken once a day, except in patients weighing less than 60 kg, who should take 5 mg once a day. Patients taking Efient should also take aspirin as prescribed by their doctors. It is recommended that treatment with Efient and aspirin continue for up to a year.

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The use of Efient is not recommended in patients over 75 years of age, unless the doctor has carefully considered its benefits and risks, and regards treatment with Efient as necessary. In this case, the 5-mg daily dose should be used following a 60-mg starting dose.

How does Efient work?

The active substance in Efient, prasugrel, 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, the platelets, sticking together (aggregating). Prasugrel stops the platelets aggregating by blocking a substance called ADP from binding to a receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent a heart attack or a stroke.

How has Efient been studied?

In one main study Efient, given as a 60-mg starting dose followed by 10-mg 'maintenance' doses, was compared with clopidogrel (another inhibitor of platelet aggregation), both medicines taken in combination with aspirin. The study involved almost 14,000 adults with acute coronary syndrome who were about to undergo percutaneous coronary intervention. The main measure of effectiveness was the reduction in the total number of cardiovascular deaths (deaths due to problems in the heart or blood vessels), heart attacks or strokes. The patients were followed up for an average of 14.5 months.

What benefit has Efient shown during the studies?

Efient was more effective than clopidogrel at reducing the total number of cardiovascular deaths, heart attacks or strokes. At the end of the study, 9% of the patients taking Efient had died from cardiovascular causes or had a heart attack or stroke (643 out of 6,813) compared with 11% of the patients taking clopidogrel (781 out of 6,795).

What is the risk associated with Efient?

The most common side effects with Efient (seen in between 1 and 10 patients in 100) are anaemia (low red blood cell counts), haematoma (a collection of blood under the skin or in a muscle), epistaxis (nosebleeds), gastrointestinal haemorrhage (bleeding in the stomach or gut), rash, haematuria (blood in the urine), bleeding from needle puncture sites, haematoma at puncture sites and bruising. For the full list of all side effects reported with Efient, see the package leaflet.

Efient must not be used in patients who have a condition that causes excessive bleeding, who have had a stroke or transient ischaemic attack (a temporary reduction in the blood supply to part of the brain), or with severe liver problems. For the full list of restrictions, see the package leaflet.

Why has Efient been approved?

The CHMP decided that Efient's benefits are greater than its risks, when given together with aspirin, for the prevention of atherothrombotic events in patients with acute coronary syndrome undergoing primary or delayed percutaneous coronary intervention. The Committee recommended that Efient be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Efient?

A risk management plan has been developed to ensure that Efient is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Efient, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Efient will make sure that educational materials are available in all Member States for doctors who will treat patients with the medicine. The materials will include information on how to prescribe the medicine safely and to remind doctors that the medicine is not recommended for patients over the age of 75 years.

Other information about Efient

The European Commission granted a marketing authorisation valid throughout the European Union for Efient on 25 February 2009.

The full EPAR for Efient can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Efient, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2016.