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Efient (*prasugrel*)

An overview of Efient and why it is authorised in the EU

What is Efient and what is it used for?

Efient is a medicine taken together with aspirin to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) in adults 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.

Efient contains the active substance prasugrel.

How is Efient used?

Efient is available as tablets to be taken by mouth 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.

The medicine can only be obtained with a prescription.

For more information about using Efient, see the package leaflet or contact your doctor or pharmacist.

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.

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What benefits of Efient have been shown in studies?

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.

Efient was shown to be 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 are the risks associated with Efient?

For the full list of side effects and restrictions with Efient, see the package leaflet.

The most common side effects with Efient (which may affect up to 1 patient in 10) 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.

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.

Why is Efient authorised in the EU?

The European Medicines Agency 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.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Efient have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Efient are continuously monitored. Suspected side effects reported with Efient are carefully evaluated and any necessary action taken to protect patients.

Other information about Efient

Efient received a marketing authorisation valid throughout the EU on 25 February 2009.

Further information on Efient can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/efient

This overview was last updated in 11-2024.