European Medicines Agency

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Zyllt
clopidogrel

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Zyllt?
Zyllt is a medicine that contains the active substance clopidogrel. It is available as pink, round tablets (75 mg).
Zyllt is a 'generic medicine'. This means that Zyllt is similar to a 'reference medicine' already authorised in the European Union (EU) called Plavix. For more information on generic medicines, see the question-and-answer document here.

What is Zyllt used for?
Zyllt is used in adults to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries). Zyllt can be given to the following groups of patients:
- patients who have recently had a myocardial infarction (heart attack). Zyllt can be started between a few days and 35 days after the attack;
- patients who have had a recent ischaemic stroke (stroke caused by failure of the blood supply to part of the brain). Zyllt can be started between seven days and six months after the stroke;
- patients with peripheral arterial disease (problems with blood flow in the arteries);
- patients who have a condition known as 'acute coronary syndrome', when it should be given with aspirin (another medicine that prevents blood clots), including patients who have had a stent inserted (a short tube placed in an artery to prevent it closing up). Zyllt can be used in patients who are having myocardial infarction with 'ST segment elevation' (an abnormal reading on the electrocardiogram or ECG) when the doctor thinks that they would benefit from the treatment. It can also be used in patients who do not have this abnormal reading on the ECG, if they have unstable angina (a severe type of chest pain) or have had a 'non-Q-wave' myocardial infarction.

The medicine can only be obtained with a prescription.

How is Zyllt used?
The standard dose of Zyllt is one 75 mg tablet once a day, taken with or without food. In acute coronary syndrome, Zyllt is used together with aspirin and treatment generally starts with a loading dose of four 75 mg tablets. This is then followed by the standard 75 mg dose once a day for at least four weeks (in ST segment elevation myocardial infarction) or for up to 12 months (in non-ST segment elevation syndrome).

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How does Zyllt work?
The active substance in Zyllt, clopidogrel, 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). Clopidogrel stops the platelets aggregating by blocking a substance called ADP from attaching to a special receptor on their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming and helping to prevent another heart attack or stroke.

How has Zyllt been studied?
Because Zyllt is a generic medicine, studies have been limited to tests to determine that it is bioequivalent to the reference medicine, Plavix. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefit and risk of Zyllt?
Because Zyllt is a generic medicine and is bioequivalent to the reference medicine, its benefit and risk are taken as being the same as those of the reference medicine.

Why has Zyllt been approved?
The Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Zyllt has been shown to have comparable quality and to be bioequivalent to Plavix. Therefore, the CHMP's view was that, as for Plavix, the benefit outweighs the identified risk. The Committee recommended that Zyllt be given marketing authorisation.

Other information about Zyllt:
The European Commission granted a marketing authorisation valid throughout the EU for Zyllt to Krka, d.d., Novo mesto on 28 September 2009.

The full EPAR for Zyllt can be found here.

This summary was last updated in 07-2009.