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EPAR summary for the public

Kengrexal

cangrelor

This is a summary of the European public assessment report (EPAR) for Kengrexal. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Kengrexal.

For practical information about using Kengrexal, patients should read the package leaflet or contact their doctor or pharmacist.

What is Kengrexal and what is it used for?

Kengrexal is a blood-thinning medicine used to reduce the occurrence of problems caused by blood clots, such as heart attack. It is used together with aspirin in adults with coronary artery disease (heart disease caused by the obstruction of the blood vessels that supply the heart) who are undergoing percutaneous coronary intervention (PCI – a surgical procedure used to unblock narrowed blood vessels that supply the heart).

Kengrexal is given to patients who have not been treated before the procedure with other blood-thinning medicines called '$P2Y_{12}$ inhibitors' (clopidogrel, ticagrelor or prasugrel) taken by mouth, and for whom treatment with these medicines is not possible or desirable.

Kengrexal contains the active substance cangrelor.

How is Kengrexal used?

Kengrexal should be given by a doctor who is experienced in the treatment of coronary disease or in PCI procedures. The medicine can only be obtained with a prescription and should be given in a hospital setting.

Kengrexal is available as a powder to be made up into a solution for injection and infusion (drip) into a vein. Treatment starts with an injection into a vein at a dose of 30 micrograms per kilogram

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bodyweight, which should last less than a minute; this is followed immediately after by an infusion at a rate of 4 micrograms per kilogram each minute. Treatment should be started before the PCI procedure, and the infusion should be continued for at least 2 hours or until the procedure is over, whichever is longer. At the discretion of the doctor, the infusion may be continued for up to four hours. At the end of the infusion, patients should be switched to maintenance treatment by mouth with clopidogrel, ticagrelor or prasugrel.

How does Kengrexal work?

The active substance in Kengrexal, cangrelor, is an antiplatelet medicine. This means that it helps to prevent blood cells called platelets from sticking together and forming blood clots, thus helping to prevent another heart attack. Cangrelor stops the platelets sticking together by blocking a substance called ADP from attaching to their surface. This stops the platelets becoming 'sticky', reducing the risk of a blood clot forming.

What benefits of Kengrexal have been shown in studies?

Kengrexal was compared with clopidogrel taken by mouth in one main study involving over 11,000 adults with coronary artery disease who were undergoing PCI. Nearly all patients also took aspirin and/or other blood-thinning medicines. The main measure of effectiveness was based on the number of patients having an 'event' such as a heart attack or clots in the heart blood vessels requiring intervention, or dying from any cause, in the 48 hours following PCI. Kengrexal was shown to be more effective than clopidogrel taken by mouth at reducing the occurrence of these events: 4.7% of patients (257 out of 5,470 patients) given Kengrexal had an event or died compared with 5.9% (322 out of 5,469 patients) of patients given clopidogrel.

Kengrexal was also investigated in one study in which it was given before surgery to patients who had been previously treated with blood-thinning medicines taken by mouth. However, the way this study was designed was considered inadequate to show a clear benefit in these patients, and the company did not pursue this use as part of the application.

What are the risks associated with Kengrexal?

The most common side effects with Kengrexal (which may affect up to 1 in 10 people) include mild and moderate bleeding and dyspnoea (difficulty breathing). The most serious side effects with Kengrexal include severe and life-threatening bleeding and hypersensitivity (allergic) reactions. For the full list of all side effects reported with Kengrexal, see the package leaflet.

Kengrexal must not be used in patients who are actively bleeding or who are at an increased risk of bleeding because of a bleeding disorder, recent major surgery or trauma, or uncontrolled high blood pressure. It must also not be used in patients who have had a stroke or mini stroke (transient ischaemic attack or TIA). For the full list of restrictions, see the package leaflet.

Why is Kengrexal approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Kengrexal's benefits are greater than its risks and recommended that it be approved for use in the EU. The medicine has been shown to be beneficial at reducing problems caused by blood clots in patients undergoing PCI who have not received previous treatment with $P2Y_{12}$ inhibitors. The fact that the medicine is given into a vein is considered useful in patients who cannot swallow and cannot take treatments by mouth.

Regarding Kengrexal's safety profile, the CHMP noted that the incidence of bleeding was higher for Kengrexal than for clopidogrel, but this was expected given the greater effectiveness of the medicine, and was offset by the fact that the activity of Kengrexal wore off quickly once the infusion was stopped.

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

A risk management plan has been developed to ensure that Kengrexal 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 Kengrexal, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Kengrexal

The European Commission granted a marketing authorisation valid throughout the European Union for Kengrexal on 23 March 2015.

The full EPAR and risk management plan summary for Kengrexal 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 Kengrexal, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2015.