22 January 2015
EMA/CHMP/45332/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Kengrexal

cangrelor

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Kengrexal 50 mg powder for concentrate for solution for infusion intended for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention and who have not received an oral P2Y12 inhibitor prior to the PCI procedure. Kengrexal should be co-administered with acetylsalicylic acid.

The applicant for this medicinal product is The Medicines Company UK Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Kengrexal is cangrelor, a platelet aggregation inhibitor ATC code: B01AC25.

Cangrelor is a direct P2Y12 platelet receptor inhibitor that blocks adenosine diphosphate (ADP)-induced platelet activation and aggregation in vitro and ex vivo. Cangrelor binds selectively and reversibly to the P2Y12 receptor to prevent further signalling and platelet activation.

The benefits with Kengrexal are its ability to inhibit platelet aggregation and co - administered with acetylsalicylic acid, prevent occurrence of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention and who have not received prior oral P2Y12 therapy.

The most common side effects are mild and moderate bleeding and dyspnoea. Serious adverse reactions associated with cangrelor in patients with coronary artery disease include severe/life threatening bleeding and hypersensitivity.

A pharmacovigilance plan for Kengrexal will be implemented as part of the marketing authorisation.

The approved indication is:

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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“Kengrexal, co-administered with acetylsalicylic acid (ASA), is indicated for the reduction of thrombotic cardiovascular events in adult patients with coronary artery disease undergoing percutaneous coronary intervention (PCI) who have not received an oral P2Y12 inhibitor prior to the PCI procedure and in whom oral therapy with P2Y12 inhibitors is not feasible or desirable."

It is proposed that Kengrexal be prescribed by physicians experienced in the treatment of the disease.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Kengrexal and therefore recommends the granting of the marketing authorisation.