24 June 2010
EMA/CHMP/392715/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Rapiscan

regadenoson

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rapiscan 400 mg solution for injection intended for use as a pharmacological stress agent for radionuclide myocardial perfusion imaging in adult patients unable to undergo adequate exercise stress. The applicant for this medicinal product is Gilead Sciences International 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 Rapiscan is regadenoson, another cardiac preparation (ATC Code C01EB21). Rapiscan was developed as a short-acting pharmacologic stress agent in conjunction with radionuclide myocardial perfusion imaging/myocardial perfusion scintigraphy because it has low yet selective affinity for the A2A-AdoR, has high potency for increasing coronary blood flow, and preferentially causes greater coronary than peripheral vasodilatation in animal models.

The benefits with Rapiscan are its ability to the potential to selectively increase coronary blood flow, while minimizing some of the side effects caused by the currently approved pharmacologic stress agents.

The most common side effects are dyspnoea, headache, flushing, chest pain, electrocardiogram ST segment changes, gastrointestinal discomfort and dizziness.

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

The approved indication is: “Rapiscan is a selective coronary vasodilator for use as a pharmacological stress agent for radionuclide myocardial perfusion imaging (MPI) in adult patients unable to undergo adequate exercise stress.” Treatment with Rapiscan is restricted to use in a medical facility where cardiac monitoring and resuscitation equipment are available.

[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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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 will be 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 Rapiscan and therefore recommends the granting of the marketing authorisation.