11 November 2021
EMA/CHMP606839/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rapiscan

regadenoson

On 11 November 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Rapiscan. The marketing authorisation holder for this medicinal product is GE Healthcare AS.

The CHMP adopted a change to the existing indication as follows:[2]

> This medicinal product is for diagnostic use only.
>
> Rapiscan is a selective coronary vasodilator for use in adults as a pharmacological stress agent for:
>
> - ~~radionuclide~~ myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress.
> - the measurement of fractional flow reserve (FFR) of a single coronary artery stenosis during invasive coronary angiography, when repeated FFR measurements are not anticipated (see sections 4.2 and 5.1).

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

[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
[2] Removed text as strikethrough

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union