EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2018
EMA/CHMP/831008/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Rapiscan

regadenoson

On 13 December 2018, 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 new indication as follows:

"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)."

For information, the full indications for Rapiscan will be as follows:[2]

"Rapiscan is a selective coronary vasodilator for use **in adults** as a pharmacological stress agent for**:**

- radionuclide myocardial perfusion imaging (MPI) in ~~adults~~ 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] New text in bold, removed text as strikethrough

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