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EMA/CHMP/500920/2014
Committee for Medicinal Products for Human Use (CHMP)

Rapiscan

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: regadenoson

Procedure No. EMEA/H/C/001176/PSUV/0014

Period covered by the PSUR: 10 April 2013 – 9 October 2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Rapiscan, the scientific conclusions of PRAC are as follows:

The PRAC considered that the overall risk/benefit of Rapiscan remained favourable however a review of a number of signals has provided important safety information.

Taking into account the review of the cases of cerebrovascular accident (CVA) reported with regadenoson, the fact that regadenoson is already known to cause TIAs and that regadenoson can cause a marked and rapid increase in blood pressure (a risk factor for intracranial haemorrhage), and hypotension and atrial fibrillation (a risk factors for ischaemic stroke), the PRAC concluded that there is a reasonable possibility that regadenoson could cause a CVA.

In addition, the MAH proposed to amend the Product Information regarding the risk of elevated blood pressure. This was endorsed by the PRAC, especially as, regadenoson could cause a marked and rapid increase in blood pressure (including hypertensive crises), which is a risk factor for CVA in susceptible individuals and has been implicated as a contributing factor in some of the cases of haemorrhagic CVA.

Furthermore, taking into account the review of a signal of prolonged or multiple seizures after aminophylline administration, and that aminophylline can decrease seizure threshold and may reduce the efficacy of anti-seizure drugs, the PRAC concluded that it is plausible that its administration to patients who experience regadenoson-induced seizure may result in longer or multiple seizures.

Therefore, in view of available data, the PRAC considered that changes to the product information of the marketing authorisation were warranted on the risks of haemorrhagic cerebrovascular accident, prolongation/worsening of regadenoson-induced seizures due to the administration of aminophylline and the risk of elevated blood pressure.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Rapiscan, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance regadenoson is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.