EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

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

International non-proprietary name: avanafil

Procedure No. EMEA/H/C/PSUSA/00010066/201412

Period covered by the PSUR: 21 June 2014 – 20 December 2014

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Scientific conclusions

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

Based on the PRAC review of data on safety and efficacy, the PRAC considers by consensus that the risk-benefit balance of medicinal products containing avanafil remains favourable but recommends that the terms of the marketing authorisation should be varied as follows:

Update of section 4.3 and 4.5 of the SmPC to add the contraindication of concomitant administration of avanafil with riociguat because of an increased risk of hypotension. The Package leaflet is updated accordingly.

The following changes to the product information of medicinal products containing avanafil are recommended (additions are marked in bold and underlined):

Summary of Product Characteristics

- Section 4.3

A contraindication should be added as follows:

The co-administration of PDE5 inhibitors, including avanafil, with guanylate cyclase stimulators, such as riociguat is contraindicated as it may potentially lead to symptomatic hypotension (see section 4.5).

- Section 4.5

Effect of avanafil on other medicinal products

[…]

Riociguat

Preclinical studies showed additive systemic blood pressure lowering effect when PDE5 inhibitors were combined with riociguat. In clinical studies, riociguat has shown to augment the hypotensive effects of PDE5 inhibitors. There was no evidence of favourable clinical effect of the combination in the population studied. Concomitant use of riociguat with PDE5, including avanafil is contraindicated (see section 4.3).

Package Leaflet

Section 2: Do not take SPEDRA if you:

The following statement should be added:

- are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.

Section 2: Other medicines and SPEDRA: Tell your doctor or pharmacist if you are already taking:

- riociguat.

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 avanafil the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing avanafil is favourable subject to the proposed changes to the product information.

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