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: melatonin

Procedure No. EMEA/H/C/PSUSA/00001963/201409

Period covered by the PSUR: 29 September 2013 – 28 September 2014

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Scientific conclusions

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

In the period covered by this PSUR 41 cases of overdose have been reported. Nine of the cases reported were associated with adverse events (AEs). These AEs have been previously described, and somnolence was the only AE reported more than once. This is already included in the Company Core Safety Information as an undesirable effect and as a symptom of overdose ("drowsiness"). It is of relevance to highlight that 19 of the 41 cases were prescribed overdose, with a median of 5 mg. Non-prescribed overdoses had a median of 6 mg. The maximum dose was 72 mg. Most reports of overdose were not associated to adverse events, and severity was mild to moderate. Considering that there was no information regarding occurrence of overdose in the Product Information, and in spite of the fact that the most reported AE is already alluded to in the present wording, section 4.9 of the SmPC should be updated to inform that cases of overdose have been reported, with somnolence as the most reported adverse event.

Therefore, in view of available data regarding overdose the PRAC considered that changes to the product information were warranted.

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

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