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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): guanfacine

Procedure No. EMEA/H/C/PSUSA/00010413/202103

Period covered by the PSUR: 18 March 2020 To 17 March 2021

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for guanfacine, the scientific conclusions of CHMP are as follows:

Suicidal events have been followed almost since the beginning of the assessment of the PSURs. Upon a request from the previous PSUR, the MAH submitted a cumulative review on this safety topic. After reviewing the information provided by the MAH, the PRAC considers that there is not enough information to include suicidal ideation in section 4.8, albeit the information included in section 4.4 is very limited and should be reinforced. Information to warn the caregivers or healthcare professionals about potential suicidal behavior should be included.

In addition, a signal of aggression was opened and closed by the MAH during the current interval. Nonetheless, there were reported cases with plausible temporal association and positive dechallenge after withdrawal or decrease in dose of GXR, and some of them without evidence of other concomitant drugs. Moreover, some cases occurred after increasing the dose of GXR. Regarding clinical trials, the percentage of cases was slightly higher in the group of GXR versus placebo, even when considering the cases considered related with the medication by the investigator. In addition, there were cases of hostility and homicidal ideation. Therefore, the PRAC considers that information about aggression should be included in the SmPC in section 4.4 and section 4.8.

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

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for guanfacine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing guanfacine is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.