



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 July 2019
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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): sufentanil

Procedure No. EMEA/H/C/PSUSA/00002798/201811

Period covered by the PSUR: 1 December 2015 To 30 November 2018



Scientific conclusions

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

Sufentanil may increase plasma serotonin level and its concomitant use with other serotonergic agents may increase the risk of serotonin syndrome.

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 sufentanil the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sufentanil 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.