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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): fluciclovine (18F)

Procedure No. EMEA/H/C/PSUSA/00010594/201911

Period covered by the PSUR: 26 May 2019 to 26 November 2019

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for fluciclovine (^{18}F), the scientific conclusions of the CHMP are as follows:

Based on literature, relatively higher than expected degree of fluciclovine (^{18}F) urinary excretion was noticed in clinical practice compared to that reported in the research studies using the standard PET/CT protocol including instruction to the patient to void before radiotracer injection. High bladder fluciclovine activity may have significant impact on the evaluation of local prostate cancer recurrence, as it may mask areas of local prostate cancer recurrence. Therefore, in view of the available data, the PRAC concluded that a recommendation concerning voiding instructions prior to administration of fluciclovine (^{18}F) was considered necessary. The product information of products containing fluciclovine (^{18}F) should be amended accordingly.

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 fluciclovine (^{18}F) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing fluciclovine (^{18}F) 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.