23 June 2022
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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): irinotecan (liposomal formulations)

Procedure No. EMEA/H/C/PSUSA/00010534/202110

Period covered by the PSUR: 23 October 2020 – 22 October 2021

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Scientific conclusions

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

In view of available data on the Hypersensitivity reactions: Angioedema and Anaphylactic/Anaphylactoid reaction and Skin reaction (Rash, Urticaria, Erythema and Pruritus) from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between irinotecan (liposomal formulations) and such reactions to be at least a reasonable possibility. The PRAC concluded that the product information of products containing irinotecan (liposomal formulations) should be amended accordingly.

In view of available data on drug-drug interactions (DDI) with flucytosine as a prodrug for 5-fluorouracil from the literature and in view of a plausible mechanism of action, the PRAC considers an interaction between irinotecan (liposomal formulations) and flucytosine to be at least a reasonable possibility. The PRAC concluded that the product information of products containing irinotecan (liposomal formulations) 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 irinotecan (liposomal formulations) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing irinotecan (liposomal formulations) 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.