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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): chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosi - centrally authorised products only)

Procedure No. EMEA/H/C/PSUSA/00010590/202410

Period covered by the PSUR: 09/10/2023 To: 09/10/2024

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosis - centrally authorised products only), the scientific conclusions of PRAC are as follows:

In view of available cumulative data on hepatic adverse reactions from the literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between chenodeoxycholic acid and increased transaminases and jaundice is at least a reasonable possibility.

The PRAC concluded that the product information of products containing chenodeoxycholic acid should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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

On the basis of the scientific conclusions for chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosis - centrally authorised products only) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing chenodeoxycholic acid (inborn error in primary bile acid synthesis, xanthomatosis - centrally authorised products only) 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.