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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): zonisamide

Procedure No. EMEA/H/C/PSUSA/00003152/202203

Period covered by the PSUR: 31/2020 to 31/03/2022

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## Scientific conclusions

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

'Use in pregnancy' is an important potential risk for zonisamide. Zonisamide must not be used during pregnancy or in women of childbearing potential not using effective contraception unless clearly necessary and only if the potential benefit is considered to justify the risk to the foetus. Clinical data on the potential risks of congenital malformation and neurodevelopmental disorders associated with the use of zonisamide during pregnancy are very limited and these risks remain unknown. The current product information indicates that the potential risk of zonisamide use during pregnancy in humans is unknown, however, it does not specifically refer to the risks of congenital malformation and neurodevelopmental disorders. It is considered that the product information should clearly reflect current available scientific knowledge in relation to these potential risks, to ensure healthcare professionals and patients are adequately informed of what is known about the risks associated with use during pregnancy. Furthermore, the risk minimisation measures in relation to use in women of childbearing potential and in pregnancy set out in the product information require amendment. Noting the requirement for women of childbearing potential to use effective contraception throughout treatment and the uncertainties about the risks to the foetus associated with use during pregnancy, pregnancy testing should be considered prior to initiation of treatment to exclude pregnancy, as is recommended for other antiepileptic drugs. Moreover, the product information should clearly reflect that re-evaluation of antiepileptic therapy should take place prior to conception and before contraception is discontinued, whilst the need for urgent review by the patient's treating doctor in the event of suspected or confirmed pregnancy should be reflected clearly in the product information. The PRAC concluded that the product information of products containing zonisamide 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 zonisamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing zonisamide 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.