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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/00003152/201703

Period covered by the PSUR: 1 April 2016 to 31 March 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

A 2014 publication in Obstetrics and Gynecology by Hernandez-Diaz et al., suggested a decrease in mean birth weight and length among neonates exposed in utero to zonisamide and an increased prevalence of 'small for gestational age' (SGA) compared to lamotrigine-exposed neonates. An update to the product information is therefore required based on these results, to add the potential for low birth weight and SGA in infants exposed to zonisamide in utero to section 4.6 of the SmPC. It is also recommended that the existing warnings in sections 4.4 and 4.6 of the SmPC be further improved regarding the need to advise women of child-bearing potential on the risks of anti-epileptic drugs in pregnancy. Corresponding changes are made to the Package leaflet.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for zonisamide the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing zonisamide is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.