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10 October 2024

Tegretol Oral Suspension, limitation of use in neonates

Dear Healthcare Professional

Novartis South Africa (Pty) Ltd, in agreement with Botswana Medicines Regulatory Authority (BoMRA) would like to inform you of the following:

Summary

- **Tegretol® (carbamazepine) 100 mg/5ml Oral Suspension (OS) is no longer recommended for neonates (below 4 weeks of age for term babies or 44 weeks post-menstrual age for pre-term babies) due to the amount of propylene glycol (PG) in this formulation.**
- **There is no change proposed in the posology of any other formulation (such as tablets) or any other the patient population**

During an ongoing procedure in another country for label update for Tegretol® 100 mg/5ml Oral Suspension, the process triggered an assessment of the amount of propylene glycol in the product. Propylene Glycol, an excipient used in this product formulation, was found to be above the threshold of (1 mg/kg/day) for neonates (refer to respective EMA guideline "*Excipients in the labelling and package leaflet of medicinal products for human use*"). The benefits do not outweigh the potential risks due to the amount of propylene glycol and therefore Tegretol® 100 mg/5ml Oral Suspension use is no longer recommended in neonates. A label update to the relevant sections in the product information and patient leaflet for Tegretol® 100 mg/5ml Oral Suspension is in process to restrict its use in neonates.

For children above 4 weeks of age (or 44 weeks post menstrual age for preterm babies), there are no changes to the label recommendations. This update only affects Tegretol® 100 mg/5ml Oral Suspension; no other formulations are impacted.

In neonates with seizures requiring Anti-Seizure Medicines (ASM), current clinical practice guidelines such as those published by the ILAE (Pressler et al 2023) should be followed for prescribing other approved first-line ASMs instead of Tegretol 100mg/5mL Oral Suspension, due to the content of propylene glycol in its formulation.

Call for reporting

Adverse reactions should be reported in accordance with the national spontaneous reporting system.

Please use the following details for reporting:

Health Authority
reportadr@bomra.co.bw

Novartis AE reporting channels;
Online: www.novartis.com/report
Email: drugsafetyeac.sac@novartis.com
Fax: +254202959146

Novartis contact point

If you have any queries, please do not hesitate to contact your respective country representative or our office at Tel: +254 20 2737771.

Yours faithfully

Dikobo Collen

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Felix Mochache
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