



EFDA

የኢትዮጵያ ምግብና መድኃኒት ባለሥልጣን
ETHIOPIAN FOOD & DRUG AUTHORITY

ቁጥር: 02/25.132/10

ቀን: 06 NOV 2024

Dear Healthcare Professionals;

Subject: Tegretol Oral Suspension, Restriction of Use in Neonates

Novartis Pharma Schweiz AG, the market authorization holder/manufacture, has notified the Ethiopian Food and Drug Authority (EFDA) that Tegretol® (carbamazepine) 100 mg/5ml Oral Suspension (OS), a product usually used for the management of generalized tonic-clonic and partial seizures, 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. Propylene glycol, one of the excipients in this product, is generally recognized as safe by the US Food and Drug Administration (FDA) for uses in food and tobacco products, pharmaceuticals, and cosmetics. However, the amount in this product is beyond the safety limit for neonates mentioned in this alert letter. Therefore, the Authority (EFDA) requests all health professionals to avoid prescribing and dispensing the medicine for neonates since the risk of using this medicine in neonates outweigh its benefits.

Please find attached the information provided by the manufacturer for additional information.

Sincerely yours,

Asnaketch Alemu
Lead executive Officer
Pharmacovigilance and
Clinical Trial



CC//

- ✚ Director General
- ✚ Deputy Director General, Medicine Sector
- ✚ Medicine Evaluation and Market Authorization Lead Executive Officer
- ✚ Pharmacovigilance and Clinical Trail Lead Executive Office
- ✚ Medicine Manufacturers Inspection and Enforcement Lead Executive Office
- ✚ Medicine Quality Control Lead Executive Office
- ✚ Branch Coordination Lead Executive Office

EFDA

Tel. 251-11-552 4122/552 4123
4-hh/Fax: 251-11-552 1392

P.O.Box: 5681

Website: www.fmhaca.gov.et
E-mail: contactefda@efda.gov.et
IN REPLY REFER TO OUR REF. NO.

መልስ በሚሰጡበት ጊዜ የእኛን ደብዳቤ ቁጥር ይጥቀሱ



Novartis Pharma Schweiz AG
Suurstoffi 14
6343, Rotkreuz
Switzerland

10 October 2024

Tegretol Oral Suspension, limitation of use in neonates

Dear Healthcare Professional

Novartis Pharma Schweiz AG, in agreement with Ethiopian Food and Drug Administration (EFDA) 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

A reminder of the need and how to report adverse reactions in accordance with the national spontaneous reporting system, including the details (e.g. name, postal address, fax number, website address) on how to access the national spontaneous reporting system:

Please use the following details for reporting:

Authority (Ethiopian Food and Drug Authority)

Email: contactefda@efda.gov.et or

pharmacovigilance@efda.gov.et

Standard ADE reporting Form (yellow)

Novartis AE reporting channels;

Online: www.novartis.com/report

Email: drugsafetysac.sac@novartis.com

Fax: [+254202959146](tel:+254202959146)

