NOVARTIS | Reimagining Medicine

Novartis New Zealand Ltd

12 Madden Street
Auckland Central 1010
New Zealand

08 September 2025

Dear Healthcare Professional

Re: Tegretol® Liquid carbamazepine 20mg/mL, limitation of use in neonates

Novartis New Zealand Limited in agreement with Medsafe would like to inform you of the following:

- Tegretol® Liquid (carbamazepine) 20mg/mL 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 to the dosage and administration of any other formulation (such as tablets) or any other patient population

During a label review by SwissMedic for Tegretol® Liquid (carbamazepine) 20mg/mL, an assessment of the amount of propylene glycol in the product was triggered. 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® Liquid (carbamazepine) 20mg/mL use is no longer recommended in neonates. The relevant sections in the data sheet (link) and consumer medicine information (CMI) (link)for Tegretol® Liquid (carbamazepine) 20mg/mL have been updated 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® Liquid (carbamazepine) 20mg/mL; 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® Liquid (carbamazepine) 20mg/mL, due to the content of propylene glycol in its formulation.

Adverse Event reporting

If you need to report an Adverse Event (AE), please submit to Patient Safety online at https://www.report.novartis.com/, email patientsafety.aunz@novartis.com or call 0800 650 555.

If you are reporting an AE from a Clinical Trial, please submit to Patient Safety at patientsafety.aunz@novartis.com

For medical enquiries or product complaints, please contact Medical Information at medinfo.phauno@novartis.com or call 0800 354 335.

Sincerely

Dr Sean Evans
Medical Head