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Direct Healthcare Professional Communication

Tegretol® 100 mg/5ml Liquid (carbamazepine): Limitation of use in neonates

November 2025

Dear Healthcare Professional,

Novartis Pharmaceuticals UK Ltd, in agreement with the Medicines & Healthcare products Regulatory Agency (MHRA), would like to inform you of the following:

Summary

- **Tegretol® (carbamazepine) 100mg/5ml Liquid is no longer recommended for neonates (below 4 weeks of age for term babies or below 44 weeks post-menstrual age for pre-term babies[1]) due to the amount of propylene glycol in this formulation**
- **There is no change proposed in the posology of any other Tegretol® formulations (such as tablets) or any other patient population**

Propylene Glycol (PG) is an excipient used in Tegretol® 100mg/5ml Liquid's formulation. During an assessment of the product's label in another country, it was found that the PG exceeds the recommended threshold for neonates (1 mg/kg/day) – please refer to the respective European Medicines Agency (EMA) guideline "*Excipients in the labelling and package leaflet of medicinal products for human use*"[2]. The Summary of Product Characteristics (SmPC)[3] has been updated to reflect this:

> **Summary**
>
> Each 1 mL of Tegretol Liquid contains 25 mg of propylene glycol, which exceeds the recommended threshold of 1 mg/kg/day for neonates. Due to underdeveloped liver and kidney function, neonates (term infants <4 weeks and pre-term infants <44 post-menstrual weeks) are unable to effectively metabolise and eliminate propylene glycol, leading to accumulation.
>
> This accumulation increases the risk of:
> - Metabolic acidosis,
> - Renal dysfunction, including acute tubular necrosis and acute renal failure,
> - Liver dysfunction.
>
> Adverse events typically resolve upon discontinuation of propylene glycol, and in severe cases, may require haemodialysis.
>
> Healthcare professionals are advised to:
>
> - Closely monitor for signs of toxicity in infants receiving this formulation.
> - Ensure the age-specific maximum daily dose is not exceeded.
> - Avoid concurrent use with substrates of alcohol dehydrogenase (e.g., ethanol), which can cause serious side effects in newborns.

Considering the above, the benefits do not outweigh the potential risks and therefore Tegretol® 100 mg/5ml Liquid use is **no longer recommended in neonates**. Please refer to the full SmPC for Tegretol® **100mg/5ml** Liquid[3], which now includes the license updates and warnings regarding PG content and neonatal safety.

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

In neonates with seizures requiring Anti-Seizure Medicines (ASM), current local clinical practice guidelines should be followed for prescribing other approved first-line ASMs instead of Tegretol® 100mg/5mL Liquid, due to the content of PG in its formulation.

References

1. Novartis Medical Risk Assessment
2. Questions and answers on propylene glycol used as an excipient in medicinal products for human use. European Medicines Agency (EMA). 2017. Accessed via: https://www.ema.europa.eu/en/documents/scientific-guideline/questions-and-answers-propylene-glycol-used-excipient-medicinal-products-human-use_en.pdf
3. Tegretol 100mg/5ml Liquid Summary of Product Characteristics. Last revised: 10 October 2025. Available at: https://www.medicines.org.uk/emc/product/1041/smpc

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Novartis contact point

If you have any questions about this letter, please contact the Novartis Medical Information department on 01276 698370 or email medinfo.uk@novartis.com

Yours faithfully,

Signed by:
Rob Hastings
Signer Name: Rob Hastings
Signing Reason: I approve this document
Signing Time: 21-Nov-2025 | 16:33:39 GMT
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Rob Hastings
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