衞生署藥物辦公室
藥物資訊及進出口管制科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND
IMPORT/EXPORT CONTROL DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

電話號碼 Tel. No.: (852) 3974 4175
詢問處 Enquiries (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:
(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

8 Sep 2025

Dear Healthcare Professionals,

Tegretol (carbamazepine): use restricted in neonates as concentration of one excipient, propylene glycol, exceeds recommended threshold

Your attention is drawn to the following European Medicines Agency's (EMA) announcement that that its safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), discussed a direct healthcare professional communication (DHPC) to inform healthcare professionals that the use of Tegretol 100 mg/5 mL oral suspension is restricted in neonates.

Tegretol 100 mg/5 mL oral suspension should not be used in neonates below 4 weeks of age for term babies, or 44 weeks post-menstrual age for pre-term babies, unless there is no other treatment option available and the expected benefit outweighs the risks. This is because this formulation of Tegretol contains 25 mg of the excipient (ingredient) propylene glycol per 1 mL, which exceeds the recommended threshold for neonates of 1 mg/kg/day. At doses of 1 mg/kg/day or higher, propylene glycol accumulates in neonates as their liver and kidneys are not mature enough to fully process and remove it from the body. This increases the risk of serious adverse reactions such as metabolic acidosis (a condition in which the blood is too acidic), renal (kidney) dysfunction including acute tubular necrosis (damage to the structures in the kidneys that filter blood), acute renal failure and liver dysfunction.

Neonates treated with Tegretol 100 mg/5 mL should be monitored by healthcare professionals, including measurements of osmolarity and/or anion gap (tests to assess the body's fluid balance and detect abnormal levels of acids in the blood). Healthcare professionals should also be aware that if Tegretol 100 mg/5 mL is given with other medicines containing propylene glycol or with any substance that is broken down by the enzyme alcohol dehydrogenase, such as ethanol, the risk of propylene glycol accumulation and toxicity is increased.

The product information of Tegretol 100 mg/5 mL is being updated to reflect its restricted use in neonates and to inform about the risk of serious adverse reactions in these patients due to the

concentration of this excipient. This restriction does not apply to other liquid formulations of carbamazepine that do not contain propylene glycol.

Tegretol 100 mg/5 mL oral suspension is a nationally authorised medicine that is used to treat various conditions including some forms of epilepsy.

The DHPC for Tegretol will be disseminated to healthcare professionals by the marketing authorisation holder, according to an agreed communication plan, and published on the direct healthcare professional communications page and/or in national registers in EU Member States.

Please refer to the following website in EMA for details:
https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-1-4-september-2025

In Hong Kong, Tegretol Syrup 2% (HK-35117) is a pharmaceutical product registered by Novartis Pharmaceuticals (HK) Limited (Novartis), and is a prescription-only medicine. So far, the Department of Health (DH) has received 10 cases of adverse events with regard to carbamazepine, but these cases were not related to neonates. In light of the above EMA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Please note that this letter serves as a mean for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(Vincent CHIANG)
for Assistant Director (Drug)