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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

13 Nov 2024

Dear Healthcare Professionals,

Tegretol Oral Suspension 2%: Update to the posology, method of administration, and limitation of use in neonates

Your attention is drawn to the Singapore Health Sciences Authority's (HSA) announcement that a Dear Healthcare Professional Letter has been issued by Novartis (Singapore) Pte Ltd to inform healthcare professionals of updates to the posology, method of administration, and limitation of use in neonates with Tegretol Oral Suspension 2% (OS) (carbamazepine). The product is indicated for epilepsy including complex or simple partial seizures (with or without loss of consciousness) with or without secondary generalization, generalized tonic-clonic seizures and mixed forms of seizures.

The revised maximum daily dose for Tegretol OS is recommended to be limited to 1200 mg/day. This recommendation is initiated to limit the amount of sorbitol intake given current constraints in sourcing sorbitol batches compliant with appropriate specifications. In addition, Tegretol 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 in this formulation.

Please refer to the following website in HSA for details:
https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/tegretol-oral-suspension---update-to-the-posology--method-of-administration--and-limitation-of-use-in-neonates

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 HSA's announcement, Novartis was contacted

and confirmed that they will apply for change of package insert of their product. The DH will remain vigilant on safety update of the drug issued by other overseas drug regulatory authorities.

Please note that this letter serves as a means 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,

p.p. (Terence MAN)
for Assistant Director (Drug)