Risk of respiratory depression and sedation associated with Epaclob 1mg/ml and 2mg/ml oral suspension® (clobazam)

07/07/2020

Dear Healthcare professional,

Ethypharm in association with the Health Products Regulatory Authority would like to inform you of the following:

Summary

- Epaclob 1mg/ml and 2mg/ml oral suspensions are not bioequivalent to clobazam tablets and care should be taken when prescribing these medications. When taking Epaclob Oral Suspension, clobazam reaches higher plasma levels than the same dose as a tablet.
- This may lead to an increased risk of respiratory depression and sedation, which may be most noticeable when switching to this medicine from tablets.

Background on the safety concern

Epaclob® may be used as an adjunctive therapy in epilepsy in adults or children over 2 years of age if standard treatment with one or more anticonvulsants has failed. Epaclob® oral suspension should only be used in children from 1 month to 2 years old, under exceptional situations, when there is a clear epilepsy indication.

Epaclob 1mg/ml and 2mg/ml oral suspensions are not bioequivalent to clobazam tablets. This is based on the results of a single-dose, randomised, cross-over bioequivalence study which found that the peak plasma level of clobazam after oral administration of Clobazam Oral Suspension 1 mg/ml and 2 mg/ml was found to be higher than that observed after administration of a reference 10 mg tablet. When taking Epaclob suspension, clobazam reaches higher plasma levels than the same dose as a tablet. This may lead to an increased risk of respiratory depression and sedation, which may be most noticeable when switching to this medicine from tablets. Therefore, caution must be taken when switching between clobazam products as the doses are not equivalent.

The risk of respiratory depression is manifested by degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion and lethargy, in more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression, rarely coma and very rarely death. As with other benzodiazepines, overdose should not present a threat to life unless combined with other CNS depressants (including alcohol).

HCPs should refer to the SmPC and PIL for full prescribing information, which are available at: www.hpra.ie.

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine. Adverse events should also be reported to Fannin via Tel +353 (0) 2907000 or E-mail: Medical@dccvital.com

Noinin Reynolds
Quality & EHS Manager

Fannin Limited, Fannin House, South County Business Park, Leopardstown, Dublin 18, Ireland.
T: +353 1 290 7000 F: +353 1 290 7111 E: info@fannin.eu
www.fannin.eu