GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

DIRECT HEALTHCARE PROFISSIONAL COMMUNICATION

Date: 15th February 2017

Title: Keppra (*Levetiracetam*) - Safety Instructions For The Risk Of Overdosing By Medication Errors

Dear Healthcare Professional,

GlaxoSmithKline safety advisory would like to inform you of the following:

Cases of accidental overdose have been reported globally with the use of Keppra oral solution; majority of cases occurred in children aged between 6 months and 11 years. Overdose in most of the cases occurred when the medicine is measured/administered using an inappropriately graduated dosing syringe or due to misunderstanding of parents and/or caregiver on how to properly measure the dose. Keppra oral solution is the preferred formulation to be used in children under the age of 6 years. Levetiracetam overdose often has no symptoms, but it may cause somnolence, agitation, depressed level of consciousness, respiratory depression or coma.

GSK is alerting prescribers to ensure accurate dosing based on child's body weight and age; and to consult parents/caregivers on how to measure the prescribed dose ensuring the safe use of Keppra.

Therapeutic indication

Keppra (Levetiracetam) is indicated as monotherapy in the treatment of:

- Partial onset seizures with or without secondary generalization in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

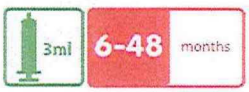
Keppra (Levetiracetam) is indicated as adjunctive therapy in the treatment of:

- Partial onset seizures with or without secondary generalization in adults, adolescents, children and infants from 1 month of age with epilepsy.
- Myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy.
- Primary generalized tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalized epilepsy.

Key messages

The current available presentation of Keppra in Saudi Market is 300 ml bottle with a 10 ml oral syringe (containing up to 1000 mg levetiracetam) graduated every 0.25 ml (corresponding to 25 mg).

The available 10ml syringe should only be used for children 4 years and onwards, however; infants and young children aged from 1 month to less than 4 years should take their doses with **external** graduated syringes as follows:

Infants aged 1 month to less than 6 months	**External** graduated syringe every 0.05 ml (corresponding to 5 mg)	
Infants and young children aged from 6 months to 48 months	**External** graduated syringe every 0.1 ml (corresponding to 10 mg)	

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سجل تجاري رقم ١٠١٠٠٩٠٧٦١ ترخيص رقم ٠٠٠٤٧-٥٩-٣٢-١٠١ رقم العضوية ٦٨٥٨٣

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Action Being Taken by GlaxoSmithKline

GSK issues this letter to inform all healthcare providers about the importance of clearly explaining the correct dosage to parents and/or caregivers guiding them on how to properly measure the prescribed dose with the appropriate graduated syringe. This letter is being sent to you after agreement with the Saudi Food and Drug Authority.

Action required by Health Care Providers

- Doctors are advised to always prescribe the dose in mg with ml equivalence based on the correct age of the patient*.
- Doctors and pharmacist are advised to educate patients and/or caregivers on how to measure the prescribed dose and to use the appropriately graduated syringe
- Healthcare providers are requested to share this information with relevant staff under their supervision

**Please refer to the attached SPC (Ref NCDS V06) for full prescribing information.*

Call for Reporting:

NPC and GlaxoSmithKline Contact details for reporting adverse drug reactions as follow:
The National Pharmacovigilance and Drug Safety Centre at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa
Or contact GlaxoSmithKline safety to report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s by email to: sa.aermi-saudi@gsk.com

Contact(s) for Further Information/Questions:

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