UCB Pharma Limited

UCB Pharma Ltd
Registered Office: 208 Bath Road, Slough, Berkshire, SL1 3WE
Main Tel: (0) 1753 534655
Main Fax: (0) 1753536632
Registration No. 209905
Registered in England and Wales

Date: 23rd July 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Keppra 100 mg/ml Oral Solution (levetiracetam):
Interim Supply of Ireland Keppra 100 mg/ml Oral Solution Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: UCB Pharma Ltd is currently experiencing supply disruption with Keppra 100 mg/ml Oral Solution (levetiracetam) in the UK.

To ensure continuity in supply during the current Covid-19 situation, UCB Pharma Ltd has obtained approval from the MHRA to supply Ireland Keppra 100 mg/ml Oral Solution product (batch number 1260; 4,999 packs), which is expected to be available on the UK market from mid May 2020 to the end of July 2020. Please note the product may remain on local shelves beyond this date.

Please note the following:

- This product is considered licensed in the UK.
- The product from Ireland has the same formulation as the UK product.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Ireland and UK product information.
- Key differences are the presence of the Polish language and the Poland and Ireland Blue Box printed on the Carton.
- Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved PIL supplied with the Ireland packs. Discard the Poland and Greek leaflet in the pack.
- For additional copies of the leaflet, please refer to https://www.medicines.org.uk/emc/ or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Keppra 100 mg/ml Oral Solution.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Image of Ireland Keppra 100 mg/ml Oral Solution Carton

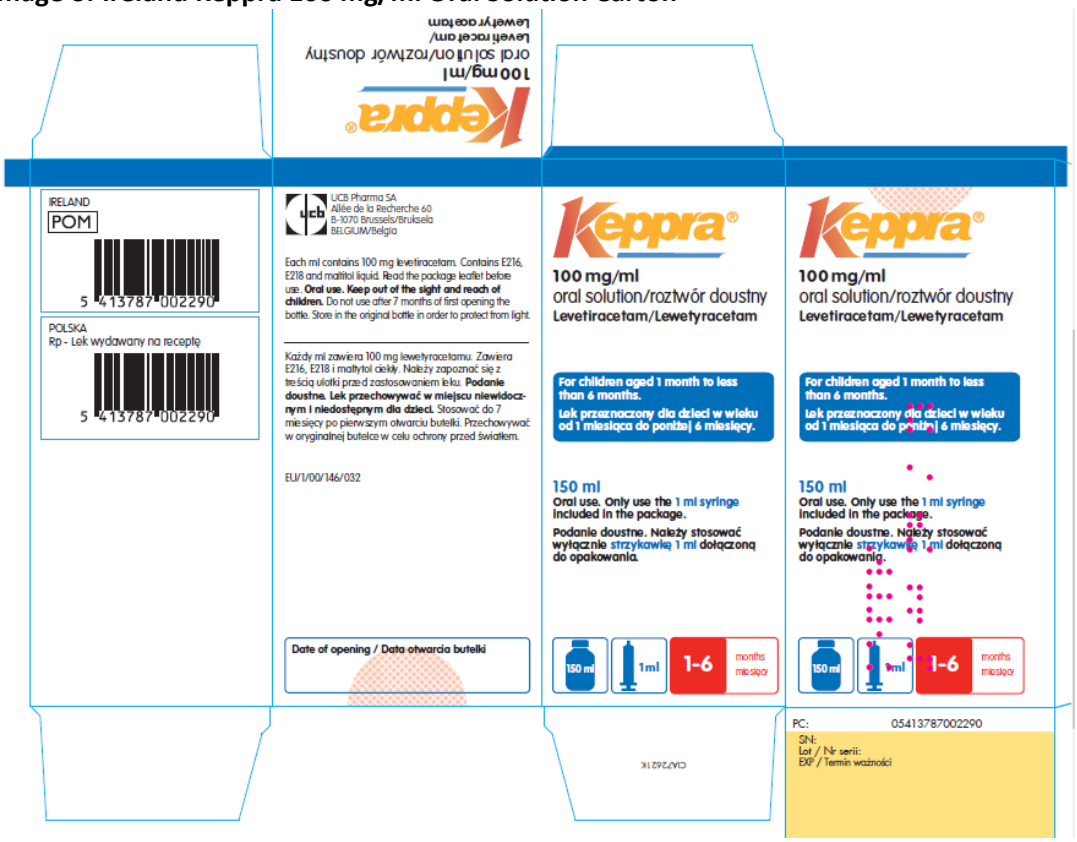
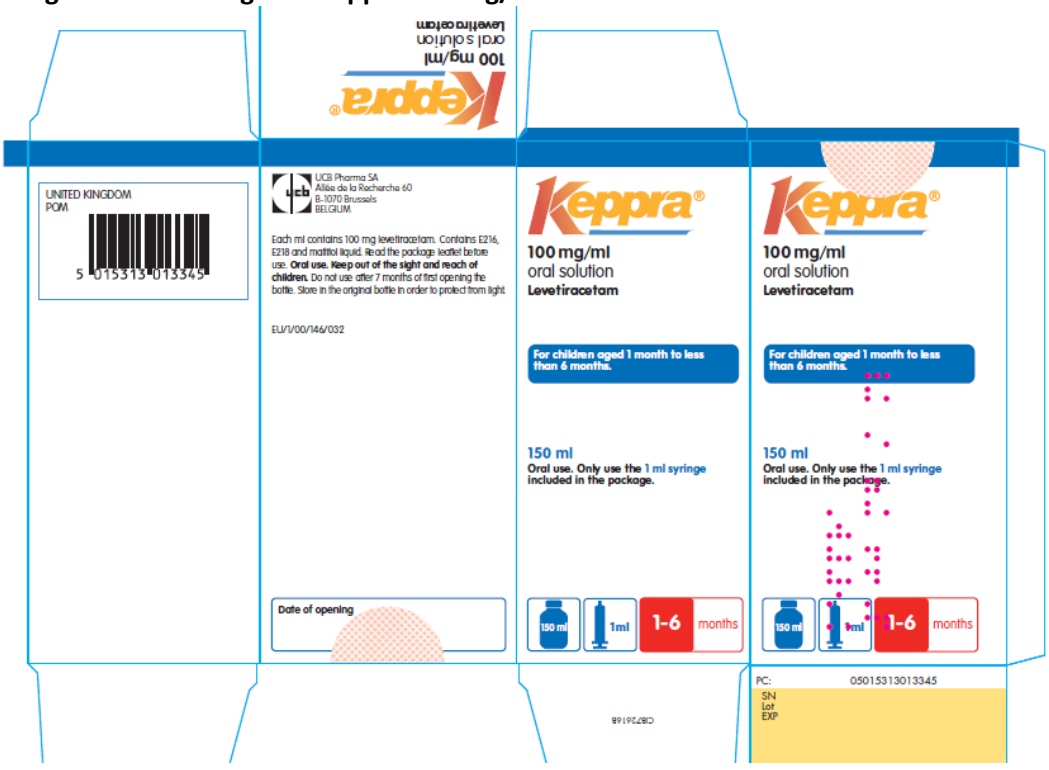


Image of United Kingdom Keppra 100 mg/ml Oral Solution Carton



Call for reporting
Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

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

Company contact point
If you have any questions about this letter or wish more information about Keppra 100 mg/ml Oral Solution, please contact UCB Pharma Ltd UK Medical Information at UCBCares UK UCBCares.UK@ucb.com or telephone 0800 2793177 or https://ucbcares.co.uk/en