Pfizer Limited
Walton Oaks, Dorking Road, Walton on the Hill,
Tadworth, Surrey KT20 7NS, UK
Telephone: +44 (0)1304 616161

Worldwide Biopharmaceutical Businesses

5th June 2019

Dear Healthcare Professional,

Re: Interim supply arrangements for Epanutin® (phenytoin) 30mg/5ml oral suspension to mitigate supply disruption

Pfizer is currently experiencing a supply disruption with Epanutin® (phenytoin) 30mg/5ml oral suspension.

There has been a delay in manufacturing and we anticipate that this will result in an out of stock period for Epanutin® (phenytoin) 30mg/5ml oral suspension from early June 2019, however we are working hard to reduce this supply gap and are exploring all options including bringing in Pfizer stock from other countries.

To help mitigate the shortage Pfizer has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to import stock of phenytoin oral suspension from Canada.

Phenytoin is a Category 1 Anti-epileptic Drug (AED) and therefore there may be clinically relevant differences between different preparations of phenytoin. Any switches to different preparations must be managed under medical supervision and may require monitoring of phenytoin serum levels.

Epanutin (phenytoin) 30mg/5ml oral suspension is indicated for control of tonic-clonic seizures (grand mal epilepsy), partial seizures (focal including temporal lobe) or a combination of these, and for the prevention and treatment of seizures occurring during or following neurosurgery and/or severe head injury. Epanutin has also been employed in the treatment of trigeminal neuralgia but it should only be used as a second line therapy if carbamazepine is ineffective or patients are intolerant to carbamazepine.

Information on Canadian presentation:

The Canadian phenytoin oral suspension is labelled as Dilantin-30 and is supplied in 250ml bottles containing 30mg/5ml phenytoin. There are small differences in the excipients: Dilantin-30 oral suspension contains Amaranth (E123) whereas Epanutin oral suspension contains Carmoisine (E122). Both suspensions are similar in colour and taste and the concentration of active ingredient (phenytoin), therefore no dosing adjustments should be necessary. The Canadian Patient Information Leaflet (PIL) contains different dosing information compared to the Epanutin PIL, therefore patients may need to be counselled to remain on their prescribed regimen and consult their doctor if they are unsure.

Patient safety is of the utmost priority to Pfizer and we are keenly aware of the importance of the supply of Epanutin® (phenytoin) 30mg/5ml oral suspension to patients. We work very hard to avoid medicines shortages but, despite our best efforts, unexpected delays can occur for which we sincerely apologise.

Normal supply of Epanutin Infatabs are much lower than the oral suspension and are only available to meet normal market demand, furthermore there is an ongoing supply issue with this product. Supplies of unlicensed Canadian Dilantin (phenytoin) Infatabs are available from Pfizer to manage this supply issue. Therefore, **patients should not be switched to Epanutin Infatabs or unlicensed Dilantin Infatabs as this may precipitate a shortage of this presentation. Additionally, Pfizer does not hold bioequivalence data for switches between the two products.**

Registered in England: No 526209
Registered Office: Ramsgate Road
Sandwich, Kent CT13 9NJ, UK

Further Information

When you order Epanutin® (phenytoin) 30mg/5ml oral suspension through the standard PIP code with Alliance Healthcare, you will receive a message to call the Pfizer Customer Contact Centre who will manage your order.

Pfizer does not recommend use of unlicensed product. However if the prescriber/healthcare professional deems it appropriate for their patient to obtain the unlicensed version, then they will need to issue a prescription for the unlicensed product

If you have any questions about this letter, please contact Pfizer Medical Information at the following address:

Medical Information, Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS United Kingdom. Telephone: **01304 616161** or visit https://www.pfizermedicalinformation.co.uk/

Safety Reporting
Suspected adverse drug reactions (ADRs) should be reported to the MHRA by use of a yellow card, which is available electronically via http://www.mhra.gov.uk/yellowcard. Suspected adverse drug reactions should also be reported to Pfizer Medical Information on **01304 616161.**

Yours faithfully,



Shaantanu Donde

UK Medical Director, Upjohn, a Pfizer division, Pfizer LTD