Pfizer Limited
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Worldwide Biopharmaceutical Businesses

23rd April 2019
Dear Healthcare Professional,

Re: Temporary supply of a different presentation in market and changes to the instructions
Epanutin® 50 mg Infatabs (phenytoin)

Pfizer would like to notify you of an important and temporary medication presentation change that may impact some of your patients.

Epanutin 50mg Infatabs (phenytoin base) 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.

There has been a delay in manufacturing and despite our best efforts, we face an out of stock for Epanutin 50 mg Infatabs until November 2019. To help mitigate the shortage, Pfizer has obtained approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) to import stock of Dilantin 50mg Infatabs (phenytoin base) from Canada.

Phenytoin is a Category 1 Anti-Epileptic Drug (AED). The active ingredient in Epanutin 50 mg Infatabs and Dilantin 50 mg Infatabs is the same, however in the absence of bioequivalence data, there may be clinically relevant differences between the two products. Any switches to different presentations must be managed under medical supervision and monitoring of phenytoin serum levels to ensure the correct dosage is being given.

Information on Canadian presentation:

The Canadian phenytoin Infatabs are labelled as Dilantin and supplied in bottles of 100 tablets with each tablet containing 50 mg phenytoin base. Canadian packs of Dilantin are considered as an unlicensed product in the UK. A copy of the product information can be found attached to this letter.

There are some differences between Dilantin and Epanutin Infatabs which prescribers will need to be aware of, a summary of these can be found below in the table below:

	Epanutin	**Dilantin**
Pack Size	200 tablet bottle	100 tablet bottle
Appearance	Yellow tablet	White tablet
Colouring agent	Contains the colouring agent E110 (sunset yellow), which imparts the Infatabs yellow colour	Does not contain E110, therefore tablets are white in colour
Concentration of alcohol	N/A	0.003 mL per tablet
Chewable properties	Chewable	Chewable

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

Pack information	Pack contains information on chewable properties	Pack information does not mention chewable properties, however bioequivalence data available to support chewed versus unchewed

Within the PIL there are differences in the way the dosage regimen is described. The dosing of both the products should be individualised as there may be wide interpatient variability in phenytoin serum levels and dosing requirements can also be variable. Please refer to the prescribing information documents of both the products which are attached to this letter.

Patient safety is of the utmost priority to Pfizer and we are keenly aware of the importance of the supply of Epanutin 50 mg Infatabs to patients. We work very hard to avoid medicines shortages but, despite our best efforts, unexpected delays can occur for which we sincerely apologise.

The Summary of Product Characteristics and Patient Information Leaflet for Epanutin 50mg Infatabs are available at: https://www.medicines.org.uk/emc/product/2259

Epanutin 30 mg/5 ml Oral Suspension remains available, however, supplies are only available to meet normal market demand**,** as such **patients should not be switched to Epanutin Oral Suspension as this may precipitate a shortage of this presentation.**

Further Information

Although Pfizer cannot recommend use of unlicensed products, under the medicines legislation, prescribers can prescribe unlicensed products for their patients if no licensed product is available to meet clinical need. However, if the prescriber/healthcare professional deems it appropriate for their patient to obtain the unlicensed version, they will need to issue a prescription for the unlicensed product Any decision to prescribe an unlicensed medicine must take into account the relevant guidance and local procedures

When you order Epanutin Infatabs 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.

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, division of Pfizer Ltd.