Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park,
Citywest Business Campus, Dublin 24.
Telephone: 01-4676500 Facsimile: 01-4676501
Freephone: 1800-460-900
www.pfizer.ie

IMPORTANT INFORMATION
FOR HEALTHCARE PROFESSIONALS AND PATIENTS
CAUTION IN USE LETTER

To be provided to the Patient
(also available on the HPRA website:
https://www.hpra.ie/homepage/medicines/medicines-information/medicines-shortages)

09 October 2019

***Supply of* EPANUTIN INFATABS 50 mg CHEWABLE TABLETS**
PA 0822/011/005
LOT CG5593 , Expiry date 03/2022

I am writing to you in connection with the supply of the above referenced product,

– **EPANUTIN INFATABS 50 mg CHEWABLE TABLETS - *PA 0822/011/005*.**

Pfizer Healthcare Ireland will be unable to supply Irish licensed packs from week commencing 04 November 2019 and has thus obtained supply of an unlicensed product, DILANTIN INFATABS 50mg CHEWABLE TABLETS (AUST R 297268), through the exempt medicinal product framework. The unlicensed product, DILANTIN INFATABS is approved in Australia and will be supplied in response to a bona fide order for this exempt presentation. HCPs should assess the differences in labelling to EPANUTIN INFATABS 50MG CHEWABLE TABLETS prior to any exempt presentation order request.

The Australian product is called **DILANTIN INFATABS 50 mg CHEWABLE TABLETS**.

Each DILANTIN INFATABS chewable tablet also contains 50 mg phenytoin and each bottle also contains 200 chewable tablets.

The current Patient Information (last revised in Ireland: 07/2019) is provided with each bottle. The current instructions on the Irish Patient Information state:

"Chew the Epanutin Infatabs or swallow them whole with plenty of water."

Please disregard this statement and instruct patients that:

"Dilantin Infatabs 50 mg chewable tablets **should** be chewed."

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There are differences in the labeling of the bottle, these differences are explained in the table below.

IRISH LICENSED PACK	**AUSTRALIAN IMPORTED PACK**
Epanutin	Dilantin
Package Leaflet provided as booklet	Package Leaflet **NOT** provided
braille: Name, strength & pharmaceutical form	no braille
"Do not store above 25°C"	"Store below 30°C"
"This product contains sucrose and sunset yellow (E110)" *(also contains same amount of saccharin)*	"Also contains sugar and saccharin" *(also contains same amount of sunset yellow (E110)*

For further details on the product please refer to the attached the Irish approved Package Leaflet.

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

If you have any questions, please contact:

Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Tel: 1800 633363 and ask for Medical Information.

Call for reporting:
You can assist us with monitoring the safety of Dilantin Infatabs 50 mg Chewable Tablets. Healthcare professionals should report any suspected adverse events associated with the use of Dilantin Infatabs 50 mg Chewable Tablets to Pfizer Medical Information on 1800 633363.
Alternatively, this information may be reported to the HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Yours sincerely,

Dr Declan O'Callaghan
Medical Director