



29th October 2019

Circular 38/19

Re: Shortage of Epanutin (Phenytoin) 50mg Chewable Tablets

Dear Pharmacist,

The HSE is aware that Epanutin (Phenytoin) Infatabs 50 mg Chewable Tablets will not be available from the 4th November 2019. Due to the nature of the product indication and given the exceptional circumstances, as a temporary measure until such time as supplies of the authorised product become available, Dilantin Infatabs 50 mg Chewable Tablets may be supplied and will be reimbursed under the GMS and Community Drug Schemes. A copy of the caution in use letter is enclosed for your information.

The product may be claimed from 1st November 2019 by using the following temporary code:

Product Description	Pack Size	Temporary Code	Reimbursement Price
Dilantin Chewable Infatabs 50 mg	200	55583	€23.39

From 1st November 2019, the HSE will not pay more than this reimbursement price for Phenytoin Infatabs 50mg Chewable Tablets under GMS (Discretionary Hardship Arrangements) or Community Drug Schemes.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'Shaun Flanagan'.

Shaun Flanagan
Primary Care Reimbursement and Eligibility



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.”

Directors of Pfizer Healthcare Ireland:
J. Molony, Dr. D. O’Callaghan,
P. Reid (Managing), M. Riordan, M. Sheppard.
Company Secretary: M. Sheppard

Registered in Ireland: No 127002
Registered Office: 9 Riverwalk,
National Digital Park,
Citywest Business Campus, Dublin 24.



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)” <i>(also contains same amount of saccharin)</i>	“Also contains sugar and saccharin” <i>(also contains same amount of sunset yellow (E110))</i>

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 HPRC 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