PLEASE DISTRIBUTE TO OTHER HEALTHCARE PROFESSIONALS IN YOUR FACILITY

Pfizer NZ
Level 1, Building B
8 Nugent Street
Auckland, 1021

19 July 2018

URGENT AND IMPORTANT
Dissolution profile of Dilantin® 30 mg and 100 mg capsules (New Formulation)

Dear Healthcare Professional

Please be advised that Pfizer has reformulated Dilantin® (phenytoin sodium) capsules 30 mg and 100 mg. While the two formulations are bioequivalent, there is a change in the dissolution properties of the capsules. The dissolution time of phenytoin manufactured using the new formulation may become longer, leading to potential changes in both absorption time and blood levels of phenytoin.

Given this change in dissolution time, it may be prudent to measure phenytoin serum levels in your patients 7 to 10 days after commencement of treatment with the reformulated capsules. If required, the dosage regimen can then be adjusted accordingly with additional serum level determinations to refine the dosage regimen further.

It is anticipated that new batches of the reformulated Dilantin® 30 mg capsules will be distributed to pharmacies from the third or fourth week of July, and new batches of reformulated Dilantin® 100 mg capsules will be distributed to pharmacies from the end of August.

Pfizer will communicate any new ordering codes as they are launched. Please continue to order as per your normal processes until further notice.

Please note that new batches will have a revised label which includes the word “Reformulation” in pink for the 30 mg capsules and in blue for the 100 mg capsules (see reproductions below). This labelling provides a clear distinction between the two formulations.

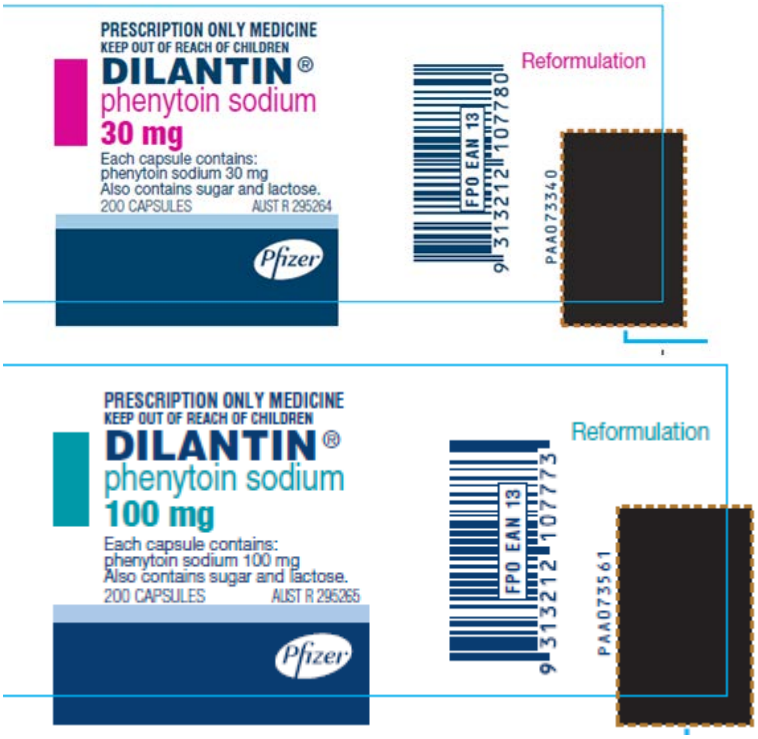
It is important that people who have received the new formulation (with “Reformulation” on the box in pink for the 30mg capsules and blue for the 100mg capsules) DO NOT change back to the older formulation with their next prescription.

We apologise for any inconvenience that this change in global manufacturing may cause you and your patients. Please contact Pfizer Medical Information on 0800 736 363 if you have any questions with regards to this reformulation.

Please report any suspected adverse events via email to Pfizer Drug Safety at medicalaffairs.anz@pfizer.com. Alternatively, suspected adverse events may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin online at https://nzphvc.otago.ac.nz/reporting or by email to nzphvc@otago.ac.nz.

Before prescribing, please review the full Dilantin® Data Sheet available at www.medsafe.govt.nz.

Revised labels for Dilantin 30 mg and 100 mg:



Kind regards,

P. Gargiulo

Pasquale Gargiulo
Associate Medical Director
Pfizer Essential Health