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Safety Notice 011/18

15 August 2018

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of Departments
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery
- Drug and Therapeutics Committee

Expert Reference Group

Content reviewed by:

- Medication Safety Expert Advisory Committee
- Director Patient Safety

Clinical Excellence Commission

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<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

August 2019

New formulation: Phenytoin (Dilantin®) capsules

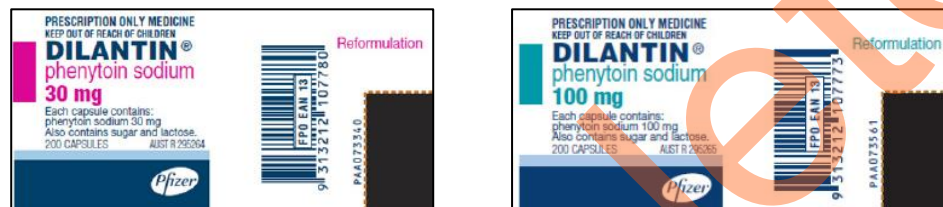
Background

Phenytoin (Dilantin®) is a commonly used antiepileptic for prophylaxis and management of seizures.

The formulation of Dilantin® 30 mg and 100 mg capsules has been altered. This alteration may cause a longer dissolution time, which leads to changes in absorption time and blood levels of phenytoin.

The new batches of reformulated phenytoin (Dilantin®) are expected to be distributed to pharmacies from the second week of August.

The reformulated phenytoin (Dilantin®) has a revised label that includes the word 'Reformulation' in pink on the 30 mg pack and in teal on the 100mg pack. See image below:



Please note that from 9 July 2018 some pharmacies and patients received the new formulation of Dilantin® 30 mg capsules.

It is important that patients who have received the new formulation (with "reformulation"— see above) DO NOT change back to the older formulation with their next script.

Implications

Phenytoin has a narrow therapeutic index, with potential significant patient safety consequences if plasma levels are too low (seizures) or too high (toxicity).

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to relevant staff at each facility.
2. All facilities should inform nursing, pharmacy and medical staff the need to:
 - a) document and communicate which formulation (if known) a patient is taking when conducting a medication history and when annotating medication charts
 - b) have phenytoin serum levels checked 7 to 10 days after commencement of the reformulated capsules
 - c) inform patients/carers if the formulation is changed during their admission
 - d) communicate the requirement for checking serum levels at transitions of care e.g. via discharge summaries to manage potential need for dose adjustments, if the patient's formulation changes during hospitalisation.
 - e) advise patients taking reformulated Dilantin® to contact their prescribers immediately should they experience any increased seizure activity (as this may indicate low serum levels) or side-effects including nausea, vomiting, insomnia, agitation, sedation, confusion, ataxia, nystagmus, diplopia, blurred vision or vertigo (as this may indicate toxic serum levels).
3. Facilities/ Drugs and Therapeutic Committees should consider:
 - a) whether patients should continue to use their own supply to avoid alteration of phenytoin therapy during the admission (especially if unrelated to the admission)
 - b) managing imprest supply of phenytoin to minimise risk.
4. Ensure a system is in place to document actions taken.