Safety Notice 011/18

New formulation: Phenytoin (Dilantin®) capsules

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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Review date

August 2019

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.