Safety Notice 043/23

Issue date
19 December 2023

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:
Directors, Managers and Staff of:

- Maternity Services
- Emergency Departments
- Nursing/Midwifery Services
- Medical Services
- Pharmacy Services
- NSW Ambulance
- Drug & Therapeutics Committees

All other relevant clinicians and clinical departments where magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution are prescribed, stored and used.

Content reviewed by:

- Medication Safety Expert Advisory Committee
- ACI Maternity and Neonatal Network
- CEC Maternity and Neonatal Stream
- Health and Social Policy Branch, Ministry of Health

Clinical Excellence Commission
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Intranet

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Safe use of magnesium sulfate heptahydrate in maternity services

Situation

Review of a recent incident identified the potential for patient harm associated with the use of magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution (a Schedule 5A product) in maternity settings. In response, the use of this formulation is no longer recommended. Reference to its use was removed from the NSW Health Policy Directive *Maternity – Management of Hypertensive Disorders of Pregnancy* (PD2011_064) and Guideline *Management of Threatened Preterm Labour* (GL2022_006) on 31 October 2023. Please note all other information in these documents (including the document number) remains unchanged.

Schedule 5A (S5A) products are included on the NSW Medicines Formulary (Formulary) where there are NSW or Australian guidelines supporting their use. Following changes to PD2011_064 and GL2022_006, magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution has been removed from the Formulary.

Background

Intravenous (IV) magnesium sulfate heptahydrate infusions are used in maternity services for the management of hypertensive disorders of pregnancy and fetal neuroprotection in pre-term labour. For these indications, IV magnesium sulfate heptahydrate is administered as an initial bolus dose of 4 g over 10 to 30 minutes, followed by a maintenance infusion of 1 g per hour (see PD2011_064 for specific dosing and administration information). Specific indications include:

- seizure prophylaxis in a woman with severe pre-eclampsia.
- prevention of further seizures in a woman with eclampsia.
- neuroprotection for those less than 30 weeks gestation if there is a risk of pre-term birth within 24 hours.

Assessment

There is a potential for patient harm associated with the use of magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution. Using this solution for both loading and maintenance dosing relies on the administering clinician to change the rate of infusion after the loading dose. This may increase the risk of the patient receiving an inadvertent overdose and magnesium toxicity. The solution also contains more than the required dose of magnesium sulfate heptahydrate for an individual over a 24-hour period.

S5A products that are not listed on the Formulary may be approved for use by the local Drug and Therapeutics Committee (DTC). **Facilities should stop using magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution effective immediately.**

Alternative IV magnesium sulfate heptahydrate formulations are available. Externally compounded pre-mixed solutions containing magnesium sulfate heptahydrate are strongly recommended for use due to the safety benefits over manually prepared solutions unless there is an immediate need to prepare manually.

Recommendations

- Current stock of magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution in each facility should be determined and removed from patient care areas immediately. Facilities should select an appropriate alternative formulation considering clinical indications for use, the availability of alternatives and local clinical guidelines/protocols.

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- Local clinical guidelines and protocols that include magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution should be reviewed and updated in accordance with current policy.
- Clinicians should consider utilising separate magnesium sulfate heptahydrate solutions for the loading dose and the maintenance infusion. For example, administering the loading dose using an extemporaneously compounded magnesium sulfate heptahydrate 4 g in 50 mL pre-mixed solution and then switching to an extemporaneously compounded magnesium sulfate heptahydrate 8 g in 100 mL pre-mixed solution for the maintenance dose.
- Administration of magnesium sulfate heptahydrate should always be via an infusion pump. Close observation and assessment (of the pregnant woman and fetus) is required for the duration of the magnesium sulfate heptahydrate infusion (see NSW Health Policy Directive *Maternity – Management of Hypertensive Disorders of Pregnancy* (PD2011_064).
- All staff responsible for prescribing, preparing, and administering magnesium sulfate heptahydrate infusions should be made aware of the changes to the NSW Health endorsed Policy Directive and Guideline and receive comprehensive education and training regarding relevant infusion protocols. LHDs/SHNs should also consider initial and ongoing competency assessments.
- Governance committees should liaise with local electronic Medication Management (eMM)/ICT teams to update configurations (for example, order sentences and product catalogues) in eMM systems where required to remove reference to magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution. Where eMM systems are in use, mechanisms are to be built to prevent selection errors at the point of prescribing and administration.
- Medicine storage areas and systems (for example, automated dispensing cabinets) should be reviewed and updated to include the alternative IV magnesium sulfate heptahydrate formulation(s) and reflect appropriate stock counts where relevant.

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where magnesium sulfate heptahydrate 40 g in sodium chloride 0.9% 500 mL pre-mixed solution may be prescribed, stored or used.
2. Develop a local action plan regarding this issue incorporating the recommendations contained within this Safety Notice.
3. Escalate any concerns to CEC-MedicationSafety@health.nsw.gov.au.
4. Report any incidents associated with the use of magnesium sulfate heptahydrate in maternity services via the local incident management system (e.g., iRIMS+).
5. Acknowledge receipt of this Safety Notice within 72 hours of receipt to CEC-MedicationSafety@health.nsw.gov.au.