MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Ephedrine sulfate 30 mg/mL ampoule for injection – 27 September 2022	
Details of affected product(s)	Ephedrine sulfate (DBL) 30 mg/mL ampoule for injection – ARTG 16325
Reason for communication	Disruption to supply due to manufacturing issues
Date issue made apparent	September 2022
Estimated resolution date	End of November 2022

Main therapeutic applications

Sympathomimetic used in the treatment of shock unresponsive to fluid replacement. It is also indicated in the treatment of hypotension secondary to spinal anaesthesia, and has accepted indications in the treatment of bronchial asthma and reversible bronchospasm (although more selective agents are now available).

Alternative agents

Pfizer is the sole sponsor of ephedrine sulfate in Australia. A product substitution has been arranged by Pfizer with the ephedrine hydrochloride SXP (Generic Health) 30 mg/mL ampoules.

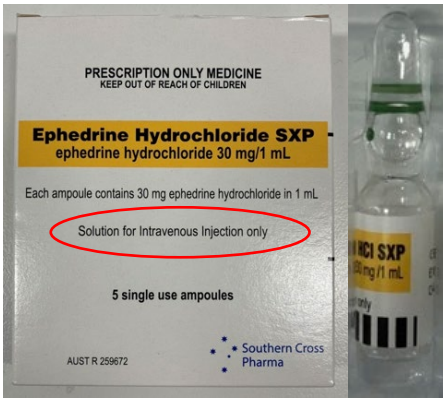
The Generic Health alternative is formulated as a different salt (ephedrine **hydrochloride**) compared to the DBL product (ephedrine **sulfate**). It is presented as a clear glass ampoule with 1 mL of liquid**.**

Remaining supply of ephedrine sulfate should be reserved for routes of administration where alternative salt formulations are not appropriate (see below).

Precautions and safety issues associated with alternative products

- The only suitable route of administration of the substitute **ephedrine hydrochloride** product is **intravenous**. This is unlike **ephedrine sulfate** which is suitable for intravenous, intramuscular and subcutaneous routes of administration. Clinicians must be aware of the differences in administration requirements.
- Electronic prescribing systems **may not** differentiate between the different ephedrine salts and therefore the routes of administration available for prescribing may require review.

ephedrine sulfate (DBL)
Images sourced from Pfizer



ephedrine hydrochloride (SXP)
Images sourced from Generic Health

Figure 1. Images of ephedrine sulfate (DBL) and ephedrine hydrochloride (SXP) outer packaging and ampoules

- The Generic Health ephedrine hydrochloride product is **not approved for use** in paediatric populations.
- The Generic Health **ephedrine hydrochloride** product contains approximately 6.3% more free ephedrine compared to **ephedrine sulfate**. The clinical impact of this has not been studied, however was deemed to be unlikely of clinical significance during the product approval process due to the need to start at the lowest effective dose and titration according to patient response.
- The approved indication for ephedrine hydrochloride is treatment of hypotension secondary to spinal anaesthesia. The Product Information does not explicitly mention the use in treatment of shock unresponsive to fluid replacement.
- Storage requirements below 25ºC remain the same, however ephedrine hydrochloride ampoules do not require protection from light.

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Impacts of this communication on clinical practice

Actions to address the disruption to the supply of ephedrine sulfate should be planned and implemented at a local level by the Drug and Therapeutics Committee and the relevant clinical specialities.

Associated regulatory or policy issues

PD2022_032 Medication Handling

Key contacts
Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
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