MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Methylprednisolone sodium succinate (Solu-Medrol Act-O-Vial) – 15 September 2023	
Details of affected product(s)	Methylprednisolone sodium succinate 40 mg powder for injection and diluent in one vial – ARTG 171991 Methylprednisolone sodium succinate 125 mg powder for injection and diluent in one vial – ARTG 171992
Reason for communication	Disruption to supply due to manufacturing issues
Date issue made apparent	August 2023
Estimated resolution date	January 2024

Main indications and use

Methylprednisolone sodium succinate injection is indicated for intravenous or intramuscular use in corticosteroid responsive conditions when oral therapy is not feasible.

Situation

There is a current disruption to the supply of methylprednisolone sodium succinate (Solu-Medrol Act-O-Vial) 40 mg and 125 mg powder for injection and diluent in one vial due to manufacturing issues. Supply is expected to return from January 2024.

Alternative agents

The following alternatives from the United Kingdom have been approved for supply in Australia until 29 February 2024, under Section 19A (S19A) of the Therapeutic Goods Act and are currently available for purchase from LINK Healthcare:

- Methylprednisolone sodium succinate (Solu-Medrone) 40 mg for injection.
- Methylprednisolone sodium succinate (Solu-Medrone) 125 mg for injection.

Precautions, safety issues and other considerations associated with alternatives

The Australian registered products and S19A alternatives are identical in active ingredients and strengths but differ in excipients, presentation and preparation. See **Table 1** below for a detailed comparison.

Table 1. Comparison of Australian registered products and S19A alternatives

	ARTG product Solu-Medrol Act-O-Vial system	**S19A alternative** Solu-Medrone powder for injection
Active ingredients and strength(s)	Methylprednisolone (as sodium succinate) 40 mg and 125 mg	Methylprednisolone (as sodium succinate) 40 mg and 125 mg
Excipients	• Monobasic sodium phosphate • Dibasic sodium phosphate • Sodium hydroxide • **Lactose monohydrate** (only contained in the 40 mg product) • Diluent: Water for injections	• Monobasic sodium phosphate monohydrate • Dibasic sodium phosphate anhydrous • **Sucrose** (only contained in the 40 mg product) • Diluent: Sterile water for injections.
Presentation	1 x 40 mg Act-O-Vial and diluent 1 mL in separate chambers. 1 x 125 mg Act-O-Vial and diluent 2 mL in separate chambers.	1 x clear glass vial fitted with a rubber stopper. Each pack also contains a vial of sterile water for injections.
Storage	Store product below 25°C prior to reconstitution. Reconstituted solution should be used immediately upon preparation. Discard any unused portion as per PD2022_032 Medication Handling.	

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	ARTG product Solu-Medrol Act-O-Vial system	**S19A alternative** Solu-Medrone powder for injection
Preparation	Preparation of the Act-O-Vial system: 1. Tap the vial containing powder to ensure that the powder is at base of vial and away from the central stopper. 2. Place the Act-O-Vial on a flat, stable surface and hold with one hand. 3. Press down firmly on the plastic activator with the palm of the other hand to force diluent into the lower compartment. 4. Gently mix the solution by turning the vial upside down a number of times. **Do not shake the vial.** 5. Remove plastic tab covering centre of stopper. 6. Sterilise top of stopper with an alcohol swab 7. Whilst on a flat surface, insert needle squarely through centre of stopper until tip is just visible. 8. Invert vial to allow the solution to flow into the top compartment and withdraw the dose.	Preparation of the powder for injection: *For the 40 mg injection –* • Remove plastic tab covering the stopper on the vials containing the powder and water for injections. • Sterilise the top of the stoppers for both vials with separate alcohol swabs. • Using a needle, withdraw 1 mL of sterile water for injections. • Insert the needle through the centre of the stopper on the vial containing the powder to reconstitute. • Gently mix the solution by turning the vial upside down a number of times. *For the 125 mg injection –* • Remove plastic tab covering the stopper on the vials containing the powder and water for injections. • Sterilise the top of the stoppers for both vials with separate alcohol swabs. • Using a needle, withdraw 2 mL of sterile water for injections. • Insert the needle through the centre of the stopper on the vial containing the powder to reconstitute. • Gently mix the solution by turning the vial upside down a number of times.

Impacts of this communication on clinical practice

- Actions to address the disruption to the supply of methylprednisolone sodium succinate 40 mg and 125 mg (Solu-Medrol Act-O-Vial) powder for injection and diluent in one vial should be planned and implemented at a local level by the Drug and Therapeutics Committee in consultation with the relevant clinicians.
- S19A alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues.

Associated regulatory or policy issues

PD2022_032 Medication Handling
PD2019_019 Coordination of responses to urgent system-level medicine or medical device issues

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au