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Dear Healthcare Professional

Shortage SOLU-MEDROL ACT-O-VIAL methylprednisolone (as sodium succinate) 125mg powder for injection and diluent in one vial AUST R: 171992, SOLU-MEDROL ACT-O-VIAL methylprednisolone (as sodium succinate) 40mg powder for injection and diluent in one vial AUST R: 171991 and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, **SOLU-MEDROL ACT-O-VIAL 125mg and 40mg** sponsored by Pfizer is currently unavailable or in short supply.

LINK has been able to arrange supply of an alternative product **Solu-Medrone methylprednisolone sodium succinate for injection 125mg** and **Solu-Medrone methylprednisolone sodium succinate for injection 40mg** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **29 February 2024** for the following indication(s):

When oral therapy is not feasible and the strength, dosage form and route of administration of the drug reasonably lend the preparation to the treatment of the condition, methylprednisolone sodium succinate is indicated only for intravenous or intramuscular use in the following conditions: Endocrine Disorders, Rheumatic Disorders, Collagen Disease, Dermatological Diseases, Allergic States, Ophthalmic Diseases, Gastrointestinal Diseases, Respiratory Diseases, Haematologic Disorders, Neoplastic Diseases, Oedematous States, Nervous System and Miscellaneous • Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy. • Trichinosis with neurologic or myocardial involvement. • methylprednisolone sodium succinate is beneficial as adjunctive therapy in the treatment of acquired immunodeficiency syndrome (AIDS) patients with moderate to severe Pneumocystis jiroveci pneumonia (PCP) when given within the first 72 hours of initial anti-pneumocystis treatment.

Solu-Medrone methylprednisolone sodium succinate for injection 125mg and 40mg is registered and marketed in United Kingdom.

Please refer to the Australian Product Information for **SOLU-MEDROL ACT-O-VIAL 125mg and 40mg** available at https://www.ebs.tga.gov.au when prescribing **Solu-Medrone methylprednisolone sodium succinate for injection 125mg and 40mg.**

Please refer to the table below for differences between the products.

Comparison between ARTG and 19A Products		
	ARTG products in short supply:	**S19A products**

Comparison between ARTG and 19A Products		
	SOLU-MEDROL ACT-O-VIAL methylprednisolone (as sodium succinate) **40mg** AND **125mg** powder for injection and diluent in one vial	Solu-Medrone methylprednisolone sodium succinate 40mg and 125mg powder for injection
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.
Excipients	Monobasic sodium phosphate Dibasic sodium phosphate Sodium hydroxide *Diluent:* Water for injections 40mg presentation also contains: Lactose monohydrate	Monobasic sodium phosphate monohydrate Dibasic sodium phosphate anhydrous *Diluent*: Sterile Water for Injections. 40mg presentation also contains: Sucrose
Reconstitution	***Directions for Using the ACT-O-VIAL System*** 1. Tap 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. **Note: Steps 1-6 must be completed before proceeding.** 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 Solutions for Intravenous Infusion*** To prepare solutions for intravenous infusion, first prepare the solution for injection as directed above. This solution may then be added to Glucose Intravenous Infusion 5%, Sodium Chloride Intravenous Infusion 0.9% or Sodium Chloride 0.9% and Glucose 5% Intravenous Infusion; the resulting admixtures should be used immediately. This solution is for SINGLE USE ONLY.	**125mg**: Reconstitute with 2mL of the accompanying solvent (Sterile Water for Injections). Reconstituted solution should be used immediately. Discard any remaining solution. **40mg**: Reconstitute with 1mL of the accompanying solvent (Sterile Water for Injections). For dilution, see enclosed leaflet. Read the leaflet for the in-use stability of reconstituted solution. Discard any remaining solution. For intravenous infusion the initially prepared solution may be diluted with 5% Dextrose (*glucose*) in water, isotonic saline (*sodium chloride 0.9%)* solution, or 5% dextrose (*glucose*) in isotonic saline (*sodium chloride 0.9%)* solution.
Storage	It is recommended that the reconstituted solution of SOLU-MEDROL be used immediately upon preparation. Discard any unused portion.	**40mg**: *After reconstitution with solvent*: Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 48 hours at 2-8°C.

Comparison between ARTG and 19A Products		
	Store reconstituted product below 25C.	It should be used immediately if stored below 25°C. *After reconstitution with solvent and further dilution with other solutions for infusion*: Chemical and physical in-use stability of the reconstituted and further diluted solution has been demonstrated for 24 hours at 2-8°C. It should be used within 3 hours if stored at 20-25°C. From a microbiological point of view, unless the method of opening/ reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user. **125mg**: After reconstitution with Sterile Water for Injections, use immediately, discard any remainder.

Adverse Event Reporting.

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with Solu-Medrone methylprednisolone sodium succinate for injection 125mg and 40mg should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Any product complaints regarding Solu-Medrone methylprednisolone sodium succinate for injection 125mg and 40mg should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation. For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully

Ameena Rabe

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Head of Unlicenced Medicines and Access Services
Link Healthcare