22 May 2023

Shortage of HEPARINISED SALINE 50IU/5mL (porcine mucous) injection ampoule and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **HEPARINISED SALINE 50IU/5mL (porcine mucous) injection ampoule (AUST R 66684).** ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

WOCKHARDT Heparin sodium 10 IU/mL (50IU/5mL) flushing solution (UK), 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 **31 August 2023.**

WOCKHARDT Heparin sodium 10 IU/mL (50IU/5mL) flushing solution (UK), is approved for use under Section 19A for the following indication:

- *Maintenance of the patency of intravenous injection devices*

WOCKHARDT Heparin sodium 10 IU/mL (50IU/5mL) flushing solution (UK), is registered in the United Kingdom and is packaged in English language.

The s19A approved UK product is identical in active ingredient, strength and excipient ingredients to the Australian registered product. The two products differ in pack sizes, please see table below outlining these differences.

	ARTG product in short supply: HEPARINISED SALINE 50IU/5mL (porcine mucous) injection ampoule (AUST R: 66684)	**S19A product** WOCKHARDT Heparin sodium 10 IU/mL (50IU/5mL) flushing solution (UK)
Presentation	Pack of **50** x **LDPE** ampoules	Pack of **10** x **glass** ampoules

4/6 Carnarvon Road
West Gosford, NSW, 2250
www.orspecpharma.com

Please refer to the Australian Product Information for the recommended dosing, in line with the above UK indications available at https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-06999-3

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 **WOCKHARDT Heparin sodium 10 IU/mL (50IU/5mL) flushing solution (UK),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at sas@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email sas@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma