12 September 2023

Shortage of HEPARIN SODIUM 5000IU/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 **HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232).** ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion - **CONTAINS PRESERVATIVE (Wockhardt),** 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 **30 April 2024.**

Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion - **CONTAINS PRESERVATIVE (Wockhardt),** is approved for use under Section 19A for the following indications:

- *Treatment of deep vein thrombosis, pulmonary embolism, unstable angina pectoris and acute peripheral arterial occlusion.*
  In extracorporeal circulation and haemodialysis.

Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion- CONTAINS PRESERVATIVE (Wockhardt), is registered in the United Kingdom and is packaged in English language.

Please note: The section 19A approved product contains Benzyl alcohol and Methyl parahydroxybenzoate. Prior to dispensing, pharmacists should determine if this product is appropriate for the patient. Must not be given to premature babies or neonates (contains benzyl alcohol).

Please note the following differences between, **HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232)** and **Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion - CONTAINS PRESERVATIVE (Wockhardt)** to be supplied under section 19A:

	HEPARIN SODIUM 5000IU/5mL (porcine mucous) injection ampoule, (AUST R 49232)	**Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion - CONTAINS PRESERVATIVE (Wockhardt) (PL 29831/0109)**
Presentation	Preservative free	Contains Preservative

Excipient ingredients	• Water for injections	• Benzyl alcohol • Methyl parahydroxybenzoate (E218) • Water for injections • Sodium hydroxide solution • Hydrochloric acid
Administration details	Heparin may be given by intermittent intravenous injection, intravenous infusion or deep subcutaneous injection.	By continuous intravenous infusion or by intermittent intravenous injection.
Pack presentation	10 x ampoules 50 x ampoules	10 x glass vials
Storage	Store below 25ºC. Discard unused portion.	Do not store above 25°C. Store in the original package Chemical and physical in use stability has been demonstrated for 28 days at 25°C. From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at 25°C. Other in use storage times and conditions are the responsibility of the user.
Additional information	Single use only.	Each multidose vial should be restricted to use in a single patient.

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 **Heparin Sodium (1,000 I.U./ml) 5,000 units in 5ml Solution for Injection or Concentrate for Solution for Infusion - CONTAINS PRESERVATIVE (Wockhardt),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@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 customerservice@orspecpharma.com.

orspec pharma
part of uniphar

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma