



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of BAXTER 0.9% SODIUM CHLORIDE 9g/L injection BP bag AHB1324 (ARTG: 48520) and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, BAXTER 0.9% SODIUM CHLORIDE 9g/L injection BP bag AHB1324 (ARTG: 48520), is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Sodium chloride 0.9% solution for infusion in FREEFLEX bag 1000mL (Fresenius Kabi, Netherlands)**. 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 **28th February 2026** for the following indication(s):



Indicated for extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss, and for restoring or maintaining the concentration of sodium and chloride ions.

Sodium chloride 0.9% solution for infusion in FREEFLEX bag 1000mL (Fresenius Kabi, Netherlands) is registered and marketed in the Netherlands by Fresenius Kabi. Although the product labelling is in Dutch, the active ingredient, strength, and dosage form are identifiable in English.

Important Administration Instructions

Pressurising intravenous solutions in flexible containers to increase flow rates can result in air embolism if the residual air if the container is not fully evacuated prior to administration.

Please note the following differences between the Australian registered and section 19A product.

	ARTG Product: BAXTER 0.9% SODIUM CHLORIDE 9g/L injection BP bag AHB1324 (ARTG: 48520)	S19A Product: Sodium chloride 0.9% solution for infusion in FREEFLEX bag 1000mL (Fresenius Kabi, Netherlands)
pH	4.0 to 7.0	No pH information provided.
Primary packaging	Viaflex PVC bag with blue twist off port protector. 	Freeflex polyolefine bag with white break off injection port protector and blue break off infusion port protector. 
Storage	Store below 30°C. Do Not freeze.	Store below 25°C. Do not store in the freezer.

For recommended dosing, please refer to the Australian Product Information (PI) for BAXTER 0.9% SODIUM CHLORIDE 9g/L injection BP bag AHB1324 (ARTG: 48520) available at: <https://www.ebs.tga.gov.au/>.

Adverse Event Reporting

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Sodium chloride 0.9% solution for infusion in FREEFLEX bag 1000mL (Fresenius Kabi, Netherlands)** should be reported by healthcare professionals and patients to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au. This information can also be reported to the TGA at: <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **Sodium chloride 0.9% solution for infusion in FREEFLEX bag 1000mL (Fresenius Kabi, Netherlands)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au.

For any orders, please contact Pro Pharmaceuticals Group on 1300 077 674 or email orders@propg.com.au.

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

Sincerely,

Sandip Manku
Director
Pro Pharmaceuticals Group