No: AB/S19A/2407008

Date: 22/07/2024

Dear Healthcare Professional,

RE: Alternative supply arrangements under Section 19A of the *Therapeutic Goods Act 1989* for registered medicines Baxter 0.9% Sodium Chloride Intravenous Infusion - ARTG 48515 (100mL) and ARTG 48520 (1000mL).

The above Australian registered medicines are in shortage due to unexpected increase in consumer demand.

Aborns Pharmaceuticals Pty Ltd has been able to arrange supply of **Sodium Chloride 0.9% solution for infusion bag 100mL and 1000mL (Lavoisier, France)** as alternative products on a temporary basis. These products are 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 2025** for the following indications:

> *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.*

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

Sodium Chloride 0.9% solution for infusion bag 100mL and 1000mL (Lavoisier, France) are identical in active ingredient and strength to the Australian registered products. They are registered and marketed in France and therefore, all the labelling is in the French language. The name of the medicine and strength is identifiable in the English language. The package leaflet is in the French language.

A comparison table between both the products is given below.

****Please pay particular attention to the different administration port protector on the section 19A approved product****

	ARTG product **BAXTER 0.9% Sodium Chloride intravenous infusion bag AUST R: 48515 and 48520**	**S19A Product** **Sodium Chloride 0.9% solution for infusion bag (Lavoisier, France)**
pH	4 to 7	4.5 to 7

Address: Level 42, 600 Bourke Street, Melbourne, VIC, 3000
Tel: 1300 117 772
Tel: +61 (0) 3 7040 8187
Email: info@aborns.com.au
Website: www.aborns.com.au

Primary Packaging (Bag Container)	*Bag container:* Blue twist off port protector for administration. There is no cap on the medication port.  	*Bag container:* Transparent pull out port protector for administration. The port protector does **not** detach. Ports are connected by a plastic membrane. There is a blue cap on the medication port. The blue cap should **not** be removed for medicine administration. 
Storage	Store below 30ºC. Do not refrigerate or freeze.	Store below 25 ºC.

Please disregard the French package leaflet enclosed within the pack and refer to the Australian Product Information for **BAXTER 0.9% Sodium Chloride intravenous infusion bag 100mL AUST R: 48515 and BAXTER 0.9% Sodium Chloride intravenous infusion bag 1000mL AUST R: 48520** when prescribing or administering **Sodium Chloride 0.9% solution for infusion bag (Lavoisier, France).** The Australian product information is available at: www.ebs.tga.gov.au

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 **Sodium Chloride 0.9% solution for infusion bags (Lavoisier, France)** should be reported by healthcare professionals and patients to the Aborns Pharmaceuticals Pty Ltd on 1300 117 772 (only within Australia) and +61 3 7040 8187 (outside Australia) or by email drugsafety@aborns.com.au. 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 Aborns Pharmaceuticals Pty Ltd on 1300 117 772 or by email info@aborns.com.au.

Yours faithfully,

Mehdi Movahednia/Director

Aborns Pharmaceuticals Pty. Ltd.

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