No: AB/S19A/2407005

Date: 17/07/2024

Dear Healthcare Professional,

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

The above Australian registered medicine is in shortage due to an unexpected increase in consumer demand.

Aborns Pharmaceuticals Pty Ltd has been able to arrange for supply of the following alternative product, registered and marketed in France, on a temporary basis:

Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 100ml (France).

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 **30 April 2025** for the following indications:

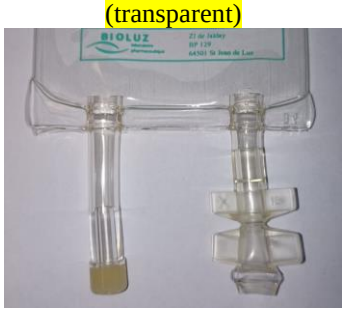
- *for extracellular fluid replacement and in the management of metabolic alkalosis in the presence of fluid loss, and for restoring or maintaining the concentration of sodium and chloride ions.*

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.

The s19A approved product is identical in active ingredient and strength to the Australian registered product. It is 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 to Australian Healthcare Professionals. The package leaflet is in the French language. The s19A medicine is in the form of solution for infusion bag with dual access, equipped with a collection site and an infusion site.

The key differences between the Australian registered products and the France registered products, are outlined in the table below:

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

	Australian registered **Baxter Sodium Chloride 0.9% IV Infusion** **AUST R 48515 (100mL)**	**<u>s19A Product</u>** **Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 100ml (France)**
pH	4 to 7	4.5 to 7
Primary Packaging (Bag Container)	*Bag Container:* VIAFLEX (PVC) Container with Twist off port protector (blue colour) 	*Bag Container:* Polyvinyl chloride (PVC) flexible bag with Twist off port protector (transparent) 
Storage condition	Store below 30ºC	Store below 25ºC

Please refer to the Australian Product Information for indications, recommended dosing and adverse reaction profile for: **Baxter Sodium Chloride 0.9% IV infusion – ARTG 48515 (100mL)** while prescribing, dispensing or administering **Sodium Chloride 0.9% Bioluz, Solution for Infusion in Dual Access PVC Bag 100ml (France)**. The Product Information is available at the TGA website: 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% Bioluz, Solution for Infusion in Dual Access PVC Bag 100ml (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 at info@aborns.com.au.

Yours faithfully,

Mehdi Movahednia/Director

Aborns Pharmaceuticals Pty. Ltd.

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