

No: AB/S19A/2407010

Date: 26/07/2024

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 48517 (250mL) and ARTG 48519 (500mL).**

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 250mL and 500mL (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 250mL and 500mL (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\*\***

	<b>ARTG product BAXTER 0.9% Sodium Chloride intravenous infusion bag AUST R: 48517 and 48519.</b>	<b>S19A Product Sodium Chloride 0.9% solution for infusion bag (Lavoisier, France)</b>
pH	4 to 7	4.5 to 7



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

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 250mL AUST R: 48517** and **BAXTER 0.9% Sodium Chloride intravenous infusion bag 500mL AUST R: 48519** 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](http://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](mailto: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](mailto:info@aborns.com.au).

Yours faithfully,

Mehdi Movahednia/Director

Aborns Pharmaceuticals Pty. Ltd.