

29<sup>th</sup> February 2024

Dear Healthcare Professional,

**Shortage of MINIRIN desmopressin acetate 10 microgram/actuation nasal spray (AUST R 59320) and alternate supply arrangement under Section 19A of the Therapeutic Goods Act 1989.**

The Australian registered medicine, MINIRIN desmopressin acetate 10 microgram/actuation nasal spray (AUST R 59320) sponsored by Ferring Pharmaceuticals Pty Ltd is unavailable due to product recall.

Medsurge has been able to arrange for the supply of **Desmopressin Nasal Spray Solution, USP 10mcg/0.1mL (Apotex, USA)** as an alternative product on a temporary basis. 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 **31 October 2024** for the following indications:

Diabetes Insipidus

- *The treatment of ADH-sensitive cranial diabetes insipidus, including treatment of post-hypophysectomy polydipsia and polyuria.*

Nocturnal Enuresis

- *The symptomatic treatment of primary nocturnal enuresis in patients who have normal ability to concentrate urine. Desmopressin nasal spray should be used only in patients who are refractory to the enuresis alarm or in patients in whom enuresis alarm is contraindicated or inappropriate, and where the oral administration of desmopressin is not feasible.*

Renal Concentrating Capacity

- *By intranasal administration to adults and children as a diagnostic test to establish renal concentrating capacity.*

**Desmopressin Nasal Spray Solution, USP 10mcg/0.1mL (Apotex, USA)** is registered and marketed in USA by Apotex Inc. and therefore all labelling is in English. Medsurge recommends that healthcare professionals refer to the Australian Product Information (PI) for recommended dosing for the above indications. The Australian Product Information for MINIRIN desmopressin acetate 10 microgram/actuation nasal spray (AUST R 59320) is available from: [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au).

A comparison table of differences between Australian registered product and the section 19A product is given below:

	<b>ARTG product: MINIRIN desmopressin acetate 10 microgram/actuation nasal spray (AUST R 59320)</b>	<b>S19A Product: Desmopressin Nasal Spray Solution, USP 10mcg/0.1mL (Apotex, USA)</b>
<b>Storage</b>	Store below 25°C. Protect from light. Do not freeze.	Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F). STORE BOTTLE IN UPRIGHT POSITION.
<b>Information given to patients</b>	The physician should carefully explain the use of the spray device and advise the patient not to inhale. Patients should be instructed to read accompanying directions on use of the spray pump carefully before use. Prime the spray before using it for the	<u>Administration</u> <ul style="list-style-type: none"> <li>• Inform caregivers for pediatric patients that administration should be supervised to ensure the patient receives the prescribed dose.</li> <li>• Inform patients that the pump must be primed prior to first use and again if</li> </ul>

	<p>first time by pressing it at least four times, or until an even spray is obtained. If the spray has not been used during the last 7 days, it is necessary to prime it again by pressing it a couple of times until an even spray is obtained before placing the nozzle in the nostril.</p> <p>Spray pump of 6 mL delivering 60 doses of 10 micrograms desmopressin acetate.</p>	<p>not used for greater than one week. Inform patients that the desmopressin nasal spray bottle delivers 50 sprays of 10 mcg each following the initial 4 priming pumps.</p> <ul style="list-style-type: none"> <li>• Inform patients to discard any solution remaining after 50 sprays since the amount delivered thereafter may be substantially less than 10 mcg of drug.</li> </ul>
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### Adverse Event Reporting

Any suspected adverse event is important for the continued monitoring of the safety of all medicines. Adverse events which are experienced with **Desmopressin Nasal Spray Solution, USP 10mcg/0.1mL (Apotex, USA)** should be reported by patients and healthcare professionals to Medsurge on 1300 788 261 or email [sales@medsurge.com.au](mailto:sales@medsurge.com.au). This information can also be reported to the TGA at: <https://www.tga.gov.au/reporting-problems>.

Any product complaints with **Desmopressin Nasal Spray Solution, USP 10mcg/0.1mL (Apotex, USA)** should be reported to Medsurge on 1300 788 261 or email [sales@medsurge.com.au](mailto:sales@medsurge.com.au).

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

For further information, please contact Medsurge on 1300 788 261 or email [sales@medsurge.com.au](mailto:sales@medsurge.com.au).

Yours faithfully,

*Ramya H. Gowda*

Senior Regulatory Affairs Officer  
Medsurge Healthcare