

**5.27 DESMOPRESSIN,  
Nasal spray (pump pack) containing desmopressin  
acetate 10 micrograms per actuation, 50 actuations,  
5 mL,  
Desmomed,  
MEDSURGE HEALTHCARE PTY LTD**

**1 Purpose of Submission**

- 1.1 The Committee Secretariat submission requested the listing of a new pack size (50 actuations, 5 mL) for the new generic brand of desmopressin nasal spray (Desmomed) for the treatment of cranial diabetes insipidus and primary nocturnal enuresis, under the same restrictions as the currently PBS-listed originator brand, Minirin® nasal spray (60 actuations, 6 mL).
- 1.2 The listing was requested at the same price applied to the pump pack level, rather than on a per actuation (dose) basis.

**2 Background**

- 2.1 Desmopressin acetate 10 microgram per actuation nasal spray, 60 actuations (Minirin nasal spray) and the Section 19A brand of desmopressin acetate 10 microgram per actuation nasal spray, 50 actuations (Desmopressin Nasal Spray USP (Apotex)) are currently listed on the PBS as General Schedule Authority Required (STREAMLINED) listings for the treatment of cranial diabetes insipidus and primary nocturnal enuresis.
- 2.2 The originator brand, Minirin nasal spray, has been in shortage since 20 July 2020 and is expected to remain unavailable until 31 March 2026. Other forms of desmopressin, including the 200 microgram tablet for both cranial diabetes insipidus and primary nocturnal enuresis indications, and the 120 microgram and 240 microgram sublingual wafers for primary nocturnal enuresis, are currently listed on the PBS, with no shortages reported in the TGA medicine shortage reports database.
- 2.3 The submission noted that the sponsor has been supplying Section 19A desmopressin nasal spray (Desmopressin Nasal Spray USP (Apotex)), which has approval for supply until 31 October 2025. There are no other alternative desmopressin nasal spray products currently listed on the PBS.

***Registration status***

- 2.4 Desmomed (50 actuations, 5 mL) was TGA registered on 27 August 2025 for the treatment of cranial diabetes insipidus, primary nocturnal enuresis, and for use as a diagnostic test to establish renal concentrating capacity.

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2.5 The TGA confirmed that the generic desmopressin nasal spray (Desmomed) can be considered equivalent to Minirin nasal spray (p2 of the TGA delegate’s overview).

**Previous PBAC consideration**

2.6 Desmomed brand of desmopressin nasal spray has not previously been considered by the PBAC.

**3 Requested listing**

3.1 The submission did not provide specific restrictions but noted that there would be no change to prescribing arrangements.

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
DESMOPRESSIN					
desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations	8711L	2	2	5	<sup>a</sup> Minirin Nasal Spray
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations	12458Q	2	2	5	<sup>a</sup> Desmopressin Nasal Spray USP (Apotex)
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations	NEW MP	2	2	5	Desmomed
<b>Restriction Summary 5266 / Treatment of Concept: 5266</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
<b>Indication:</b> Cranial diabetes insipidus					

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DESMOPRESSIN					
desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations	8712M	1	1	5	<sup>a</sup> Minirin Nasal Spray
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations	12459R	1	1	5	<sup>a</sup> Desmopressin Nasal Spray USP (Apotex)
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations	NEW MP NP	1	1	5	Desmomed
<b>Restriction Summary 5342 &amp; 5267 / Treatment of Concept: 5342 &amp; 5267</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	<b>Indication:</b> Primary nocturnal enuresis				

- 3.2 The current listings of Minirin nasal spray (PBS item codes: 8711L and 8712M) and the Section 19A brand (PBS item codes: 12458Q and 12459R) include the following Administrative Advice: “Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations in the case of a shortage.” This advice enables substitution of these brands at the pharmacy level during the shortage, supporting continued patient access to desmopressin nasal spray without requiring a new prescription, despite the difference in pack size.
- 3.3 The submission did not request that Desmomed (50 actuations, 5 mL) be considered equivalent to the currently PBS-listed Minirin nasal spray (60 actuations, 6 mL) for the purposes of substitution (i.e., ‘a’-flagged to each other in the Schedule).

## 4 Consideration of the evidence

### *Sponsor hearing*

- 4.1 There was no hearing for this item.

### *Consumer inputs*

- 4.2 The PBAC noted that no consumer inputs were received for this item.

### *Economic analysis*

- 4.3 The submission presented an economic analysis for the new generic desmopressin nasal spray (Desmomed) compared to the currently PBS-listed Minirin nasal spray and the Section 19A brand (Desmopressin Nasal Spray USP (Apotex)), based on an equivalent price per pump pack rather than on a per actuation (dose) basis.
- 4.4 Table 1 provides a comparison of the price of desmopressin nasal sprays across the different brands.

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Table 1: Economic analysis

Brand	Minirin nasal spray	Desmopressin Nasal Spray USP (Apotex)	Desmomed
PBS item codes	8711L & 8712M	12458Q & 12459R	New
Pack size (actuations)	60	50	50
AEMP per pump pack	\$41.29 <sup>a</sup>	\$99.31 <sup>a</sup>	\$41.29
AEMP per actuation	\$0.69	\$1.99	\$0.83

Source: Page 4 of the submission

Abbreviations: AEMP = approved ex-manufacturer price

<sup>a</sup> Approved ex-manufacturer price as of October 2025

4.5 The submission claimed that the proposed ex-manufacturer price (EMP) for Desmomed is lower than that of the Section 19A brand. However, the proposed EMP is higher than that of Minirin nasal spray, on a per actuation (dose) basis.

**Estimated PBS usage and financial implications**

4.6 Refer to Table 2 which presents the estimated extent of use, cost of the new generic brand of desmopressin nasal spray (Desmomed) to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

4.7 The submission stated that the estimated net saving to the PBS/RPBS from the listing of Desmomed is \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million).

Refer to Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use<sup>a</sup></b>						
Number of scripts dispensed for Section 19A desmopressin nasal spray	-█████ <sup>1</sup>	-█████ <sup>1</sup>	-█████ <sup>1</sup>	-█████ <sup>1</sup>	-█████ <sup>1</sup>	-█████ <sup>1</sup>
Number of scripts dispensed for Desmomed	█████ <sup>1</sup>	█████ <sup>1</sup>	█████ <sup>1</sup>	█████ <sup>1</sup>	█████ <sup>1</sup>	█████ <sup>1</sup>
<b>Estimated financial implications of Desmomed (50 actuations, 5 mL)</b>						
Cost to PBS/RPBS less co-payment	\$█████ <sup>2</sup>	\$█████ <sup>2</sup>	\$█████ <sup>2</sup>	\$█████ <sup>2</sup>	\$█████ <sup>2</sup>	\$█████ <sup>2</sup>
<b>Estimated financial implications of Section 19A desmopressin nasal spray (50 actuations, 5 mL)</b>						
Cost to PBS/RPBS less co-payment	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>	-\$█████ <sup>2</sup>

<sup>a</sup> Assuming number of scripts per patient per year as estimated by the submission.

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Utilisation and cost model workbook

The redacted values correspond to the following ranges:

<sup>1</sup> 500 to < 5,000

<sup>2</sup> \$0 to < \$10 million

4.8 The submission estimated the number of scripts for desmopressin nasal sprays for all PBS-listed indications using the number of scripts dispensed for the Section 19A desmopressin nasal spray from the year 2024, which may not accurately reflect the total market. The submission assumed that, once the new generic brand of

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desmopressin nasal spray is PBS-listed, it would substitute for the Section 19A brand, and that net savings to the PBS/RPBS would arise from the price difference between Desmomed and the Section 19A brand. While the originator brand, Minirin nasal spray, has been in shortage since 20 July 2020 and is anticipated to return to market on 31 March 2026, the proposed price per actuation for Desmomed is higher than that of Minirin nasal spray. Overall, the estimated net savings to the PBS/RPBS would likely be overestimated.

## 5 PBAC Outcome

- 5.1 The PBAC recommended listing a new brand of desmopressin nasal spray (Desmomed) with a new pack size (50 actuations, 5 mL) for the treatment of cranial diabetes insipidus and primary nocturnal enuresis, under the same restrictions as the currently PBS-listed originator brand, Minirin® nasal spray (60 actuations, 6 mL).
- 5.2 The PBAC recommended that the new brand of desmopressin nasal spray (Desmomed, 50 actuations) be cost-minimised to Minirin nasal spray (60 actuations) on a per actuation (dose) basis.
- 5.3 The PBAC noted the ongoing shortage of Minirin nasal spray and the scheduled cessation of approval for supply under Section 19A for Desmopressin Nasal Spray USP (Apotex), effective 31 October 2025. In the absence of alternative PBS-listed desmopressin nasal spray products, the PBAC considered there to be a clinical need for an additional brand to mitigate the supply shortage and support continued patient access.
- 5.4 The PBAC noted that the TGA has established bioequivalence between Desmomed and the originator brand, Minirin nasal spray.
- 5.5 The PBAC advised that Desmomed (50 actuations, 5 mL), under Section 101 (4AACD) of the *National Health Act*, be considered equivalent to Minirin nasal spray (60 actuations, 6 mL) for the purposes of substitution (i.e., 'a'-flagged to each other in the Schedule), with the following administrative advice: 'Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.' Substitution of these brands at the pharmacy level is allowed to support continued patient access to desmopressin treatment without the need for a new prescription, despite the difference in pack size.
- 5.6 The PBAC noted that the submission estimated a net saving to the PBS/RPBS of \$0 to < \$10 million over six years, assuming Desmomed would substitute for the Section 19A brand upon PBS listing. The estimated saving is attributed to the price difference between Desmomed and the Section 19A brand. However, the estimated savings would only be realised while the Section 19A listing for desmopressin remains active, therefore, the PBAC considered the estimated net impact to the PBS/RPBS to be uncertain.

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- 5.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Desmomed is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Minirin nasal spray, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.8 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.
- 5.9 The PBAC noted the ongoing shortage of Minirin nasal spray and the scheduled cessation of approval to supply Desmopressin Nasal Spray USP (Apotex) under Section 19A, effective 31 October 2025. In the absence of alternative PBS-listed products, the PBAC considered there to be a clinical need for an additional brand to support continued patient access.
- 5.10 The PBAC advised that Desmomed and Minirin nasal spray should be considered equivalent for the purposes of substitution (i.e., ‘a’ flagged in the Schedule) under Section 101 (4AACD) of the *National Health Act*.

**Outcome:**

Recommended

## 6 Recommended listing

Add new item as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DESMOPRESSIN					
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations	NEW MP	2	2	5	<sup>a</sup> Desmomed
<b>Restriction Summary [5266] / Treatment of Concept: [5266]</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
Prescribing rule level	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.				
<b>Indication:</b> Cranial diabetes insipidus					

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MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DESMOPRESSIN						
desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations		NEW MP NP	1	1	5	<sup>a</sup> Desmomed
<b>Restriction Summary [5342] / Treatment of Concept: [5342]</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.					
<b>Indication:</b> Primary nocturnal enuresis						
<b>Population criteria:</b>						
Patient must be 6 years of age or older						
<b>Clinical criteria:</b>						
Patient must be refractory to an enuresis alarm						
<b>Caution:</b> Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.						
<b>Administrative Advice:</b> Not to be used in preference to enuresis alarms.						
<b>Restriction Summary [5267] / Treatment of Concept: [5267]</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations.					
<b>Indication:</b> Primary nocturnal enuresis						
<b>Population criteria:</b>						
Patient must be 6 years of age or older						
<b>Clinical criteria:</b>						
Patient must be one in whom an enuresis alarm is contraindicated						
<b>Caution:</b> Desmopressin nasal spray may be associated with an increased risk of hyponatraemia compared to the oral formulations.						
<b>Prescribing Instructions:</b> The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated						
<b>Administrative Advice:</b> Not to be used in preference to enuresis alarms.						

**Flow-on changes:**

Amend the existing Administrative Advice in Minirin nasal spray listings as follows:

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26897 New AA	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form desmopressin acetate 10 microgram/actuation nasal spray, 50 actuations can be substituted for desmopressin acetate 10 microgram/actuation nasal spray, 60 actuations. <del>in the case of a shortage.</del>
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***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## **9 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **10 Sponsor's Comment**

The sponsor had no comment.