

**6.21 HYPROMELLOSE,
Eye drops 3 mg per mL, 10 mL,
Revive Tears[®],
Petrus Pharmaceuticals Pty Ltd**

1 Purpose of Application

- 1.1 The Committee Secretariat submission sought a Restricted Benefit listing for a new generic brand of hypromellose 3 mg per mL eye drops (Revive Tears[®]).

2 Background

Registration status

- 2.1 Revive Tears was registered on the ARTG on 16 December 2020 as a medical device (eye lubricant) with an intended purpose that includes the temporary relief of symptoms due to dry eye (e.g. burning, irritation and discomfort). The product is also suitable for use with contact lenses.
- 2.2 The submission stated that solutions such as ‘artificial tears’ that do not contain pharmacologically active ingredients do not require bioequivalence studies; it is therefore not possible for the TGA to provide an equivalence statement for such a product.

Previous PBAC consideration

- 2.3 The PBAC has not previously considered a submission for Revive Tears.

For more detail on PBAC’s view, see section 5 PBAC outcome.

3 Requested listing

- 3.1 The submission requested that Revive Tears be made available through the PBS under the same circumstances as the existing PBS-listed brands, Genteal[®] and In a Wink Moisturising[®], as a Restricted Benefit for the treatment of severe dry eye syndrome (including Sjogren’s syndrome).

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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HYPROMELLOSE hypromellose 0.3% w/w eye drops, 10 mL	11625W 11634H	1	1	5	Revive Tears
Restriction Summary [6073] / Treatment of Concept: [6073]					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input checked="" type="checkbox"/> Optometrists <input type="checkbox"/> Midwives					
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Severe dry eye syndrome, including Sjogren's syndrome					

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HYPROMELLOSE hypromellose 0.3% w/w eye drops, 10 mL	11643T	1	1	11	Revive Tears
Restriction Summary [6098] / Treatment of Concept: [6098]					
Category / Program: GENERAL – General Schedule (Code GE)					
Prescriber type: <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives					
Restriction Level / Method: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Severe dry eye syndrome, including Sjogren's syndrome					
Clinical criteria:					
Patient must be receiving treatment under a GP Management Plan or Team Care Arrangements where Medicare benefits were or are payable for the preparation of the plan or coordination of the arrangements.					
Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
Administrative Advice: No increase in the maximum number of repeats may be authorised.					

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted that this item received no consumer comments.

Clinical claim

4.3 The submission included the ARTG certificate, ARTG record summary and product leaflet for Revive Tears. The sponsor claimed that Revive Tears is pharmaceutically equivalent to Genteal and In a Wink Moisturising.

Pricing considerations

- 4.4 The submission requested an approved ex-manufacturer price (AEMP) of \$ [REDACTED] and a dispensed price for maximum quantity (DPMQ) of \$ [REDACTED]. The PBAC noted that the AEMP for the existing brands is slightly higher at \$2.08; the DPMQ for In a Wink Moisturising is \$14.51, while Genteal has a brand price premium (DPMQ is \$18.60).

Estimated PBS utilisation and financial implications

- 4.5 NPS Medicinewise undertook two separate analyses of ocular lubricants for severe dry eye syndrome for consideration by the Drug Utilisation Sub-Committee (DUSC) in February 2021. The first was a MedicinesInsight cohort analysis based on general practice data and the second was a 10% PBS sample.
- 4.6 The DUSC analysis showed that, of the multidose preservative containing (PC) ocular lubricants listed on the PBS for severe dry eye syndrome (including Sjogren's syndrome), Genteal and In a Wink Moisturising were two of the 17 available brands as at December 2020. In 2019 (calendar year) there were 1,099,836 prescriptions (PBS and RPBS) dispensed for multidose PC ocular lubricants (compared to 1,633,943 prescriptions in 2013). Of these prescriptions, 359,973 were dispensed for Systane® (polyethylene glycol-400 + propylene glycol), which accounted for 32.7% of all PC ocular lubricants and 19.4% of all ocular lubricants (Item 7.2, Report 1 and Report 2, DUSC February 2021).
- 4.7 According to the submission, there were 80,000 to < 90,000 prescriptions (PBS and RPBS) dispensed for hypromellose 3 mg per mL eye drops (Genteal and In a Wink Moisturising) in 2020 (calendar year).
- 4.8 The submission estimated that the proposed generic brand listing for Revive Tears would result in 500 to < 5,000 prescriptions in Year 1, increasing to 10,000 to < 20,000 prescriptions in Year 6.
- 4.9 Based on the requested DPMQ of \$ [REDACTED], the submission estimated there would be a net cost saving to the PBS/RPBS from listing Revive Tears over six years (see Table 1).
- 4.10 As a Committee Secretariat submission, the financial estimates have not been independently evaluated.

Table 1: Estimated use and financial implications

	Year 1 (2021)	Year 2 (2022)	Year 3 (2023)	Year 4 (2024)	Year 5 (2025)	Year 6 (2026)
New listing						
Total number of scripts	█ ¹	█ ²	█ ²	█ ³	█ ³	█ ³
Cost of Revive Tears* to PBS/RPBS (excl. patient copayments)	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴	\$█ ⁴
Affected listings						
Total number of scripts	-█ ¹	-█ ²	-█ ²	-█ ³	-█ ³	-█ ³
Cost to PBS/RPBS of Genteal and In A Wink Moisturising) (excl. patient copayments)	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴
Estimated net financial implications						
Net cost to PBS/RPBS	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴

Source: Submission utilisation and cost model workbook

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

² 5,000 to < 10,000

³ 10,000 to < 20,000

⁴ \$0 to < \$10 million

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of a new generic brand of hypromellose 3 mg per mL eye drops (Revive Tears), under the same circumstances as the existing PBS-listed brands, Genteal and In a Wink Moisturising, for the treatment of severe dry eye syndrome (including Sjogren's syndrome).
- 5.2 The PBAC noted that the proposed AEMP for Revive Tears is slightly lower than the existing brands and that the Committee Secretariat submission estimated there would be a net cost saving to the PBS/RPBS over six years.
- 5.3 The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953*, that Revive Tears should be treated as equivalent to Genteal and In a Wink Moisturising for the purposes of substitution (i.e. 'a' flagged).
- 5.4 Consistent with the existing hypromellose brands, the PBAC advised that Revive Tears is suitable for prescribing by nurse practitioners.
- 5.5 Consistent with the existing hypromellose brands, the PBAC advised that the Early Supply Rule should not apply to Revive Tears.
- 5.6 The PBAC advised that because Revive Tears is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Genteal and In a Wink Moisturising, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by

the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.

- 5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new item:

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Indication: Severe dry eye syndrome, including Sjogren's syndrome					

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This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

7 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.

8 Sponsor's Comment

The sponsor had no comment.