5.23 POLYETHYLENE GLYCOL 400 WITH PROPYLENE GLYCOL, Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28, Systane®, ALCON LABORATORIES (AUSTRALIA) PTY LTD

1 Purpose of Submission

1.1 The Category 4 submission requested listing a new 28 x 0.8 mL unit dose pack size (28-pack) of polyethylene glycol-400 0.4% with propylene glycol 0.3% (Systane®) for the treatment of severe dry eye syndrome.

1.2 Listing was requested based on a cost-minimisation basis versus Systane 30 x 0.8 mL unit doses (30-pack).

1.3 The submission advised that from 1 May 2026, the sponsor's global manufacturing facilities will be transitioning to the 28-pack and that the 30-pack will be discontinued. It is expected that the sponsor intends to delist the 30-pack. The sponsor was advised that delisting a product from the PBS requires a separate delisting request to be lodged via the Health Products Portal (HPP).

2 Background

2.1 At the time of consideration, Systane 30-pack was listed on the PBS as Authority Required (STREAMLINED) listings for the treatment of severe dry eye syndrome.

Registration status

2.2 Systane was registered as a tears substitute medical device with the Therapeutic Goods Administration (TGA) on 3 September 2010 under the term "Lubricant, eye".

Previous PBAC consideration

2.3 At its November 2021 meeting, the PBAC recommended listing the 30-pack in place of the 28-pack. This current submission seeks to relist the 28-pack and delist the 30-pack. At the time, the PBAC noted that the submission estimated a small net save to PBS/RPBS. However, the PBAC considered the estimated save to be uncertain and likely minor.

3 Requested listing

3.1 The submission requested the following consistent with the maximum quantity and number of repeats for PBS item codes: 13100L, 13113E and 14520F.

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	NEW MP NP	2	2	5	Systane
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	NEW OP	2	2	5	Systane
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	NEW MP NP OP	4	4	5	Systane

Concept ID (for internal Dept. use)	Category / Program: ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Optometrists |☒ Medical practitioners |☒ Nurse practitioners
	Restriction type: ☒Authority Required (Streamlined)
7869	**Indication:** Severe dry eye syndrome

4 Comparator

4.1 The submission proposed the 30-pack as the only comparator. The PBAC considered this was appropriate.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer input

5.2 The PBAC welcomed input from one individual who has used polyethylene glycol 400 with propylene glycol for their own health condition. The individual described the significant impact of severe dry eye syndrome on their everyday life, including progressive vision loss. They noted they are commencing injections in their eye and expressed concern that, as polyethylene glycol is not PBS-listed, ongoing treatment is expensive and less accessible.

5.3 The PBAC noted the individual's experience and acknowledged the burden that severe dry eye syndrome can have on quality of life. The PBAC also clarified that multiple forms of polyethylene glycol 400 with propylene glycol, including Systane single-dose units, are currently PBS-listed for severe dry eye syndrome. This includes

preservative-free options suitable for patients who are sensitive to preservatives in multi-dose eye drops.

5.4 The PBAC reaffirmed its commitment to supporting access to effective and affordable treatments for severe dry eye syndrome, and to providing clear information about PBS-listed options for patients and prescribers.

Clinical data

5.5 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was reasonable.

Economic analysis

5.6 As a Category 4 submission, the economic analysis was not independently evaluated.

5.7 The submission presented a cost-minimisation approach of the 30-pack compared with the 28-pack, requesting the same Approved Ex-Manufacturer Price (AEMP) per dose and assuming an equi-effective dose of 1 unit to 1 unit.

5.8 The cost-minimisation approach (CMA) is further detailed in

5.9 Table 1.

Table 1: Cost-minimisation approach of the 30-pack to the 28-pack

	Form	Maximum quantity (packs)	Maximum quantity (units)	AEMP per pack	AEMP per dose unit	DPMQ
PBS items 13113E and 13100L						
Current	Eye drops, 4 mg – 3 mg per mL, single dose units 0.8 mL, 30	2	2	$9.74	$0.32	$34.74
Proposed	Eye drops, 4 mg – 3 mg per mL, single dose units 0.8 mL, 28	2	2	$9.09	$0.32	$33.34
PBS item 14520F (60-day prescription)						
Current	Eye drops, 4 mg – 3 mg per mL, single dose units 0.8 mL, 30	4	4	$9.74	$0.32	$55.68
Proposed	Eye drops, 4 mg – 3 mg per mL, single dose units 0.8 mL, 28	4	4	$9.09	$0.32	$52.88

Source: Table 1, p1 of submission main body, PBS Ex-manufacturer prices (excluding Efficient Funding of Chemotherapy) – 1 September 2025, submission economic workbook.

Estimated PBS usage and financial implications

5.10 The submission claimed that the change in pack size is expected to result in a small additional cost to the PBS/RPBS due to wholesaler and pharmacy mark-ups and fees. The wholesaler and pharmacy mark-ups and fees per pack are the same between the 30-pack and 28-pack despite the AEMP being reduced (AEMP reduced by 6.7% but DPMQ reduced by 4.0%). Therefore, due to an increase in packs/patient/year from

12.17 for the 30-pack to 13.04 for the 28-pack, the additional cost is the cumulation of the fees that contribute to the calculation of the DPMQ.

5.11 The submission used a market share approach, assuming a 100% substitution of the 30-pack to the 28-pack and no other changes in the market. This will not happen instantly as the 30-pack, if delisted, will have a supply only period where patients will transition. This approach also assumes that patients will not switch to another ocular lubricant that has a larger pack size. However, if the 28-pack is listed before the 30-pack is delisted, the sponsor will need to ensure the overlap period is factored into the estimates.

5.12 The submission estimated that 900,000 to < 1,000,000 scripts of the 28-pack would be supplied over the first six years of listing (100,000 to < 200,000 in Year 1 to 100,000 to < 200,000 in Year 6). The estimated net financial cost to the PBS/RPBS is therefore $0 to < $10 million over six years ($0 to < $10 million in Year 1 to $0 to < $10 million in Year 6).

5.13 Table 2**Error! Reference source not found.** presents the estimated extent of use, cost of to the PBS/RPBS and the net financial implications to the PBS/RPBS. No testing or medical imaging is associated with the listing and therefore there was no impact to the MBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of polyethylene glycol-400 with propylene glycol (28 x 0.8 mL)						
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications of polyethylene glycol-400 with propylene glycol (30 x 0.8 mL)						
Cost to PBS/RPBS less co-payment	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][2]

[a] Assuming 13.04 scripts per patient per year, as estimated by the submission.
Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Sheets 3b, 4b, 5 of Utilisation and Cost Model Workbook
The redacted values correspond to the following values:
[1] *100,000 to < 200,000*
[2] *$0 to < $10 million*

6 PBAC Outcome

6.1 The PBAC recommended listing the 28-pack at the same price per dose as proposed by the submission, under the same circumstances. The PBAC further noted that it had made recommendations at this meeting (item 9.01 refers) to alter the circumstances under which preservative-free ocular lubricant eye drops are declared pharmaceutical benefits and that these changed circumstances would apply to the listing of this new

medicinal product pack.

6.2 The concentration of active ingredients was equal for both Systane 28-pack and Systane 30-pack. They were considered different pack sizes for the same medication. Therefore, the PBAC advised the equi-effective dose was 1 treatment of Systane 28-pack equals 1 treatment of Systane 30-pack (see Table 1).

6.3 The PBAC considered that estimates for utilisation were reasonable.

6.4 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the 28-pack is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the lowest cost ocular lubricant, 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.

6.5 The PBAC noted that this submission is not eligible for an Independent Review as the PBAC made a positive recommendation.

Outcome:
Recommended

7 Recommended listing

7.1 Pending implementation of the PBAC recommendations made at item 9.01 – 'review of ocular lubricants for the treatment of severe dry eye syndrome' at this meeting, should this item's recommendation proceed before item 9.01, add a new medicinal product pack that has 28 x 0.8 mL unit doses shown in italics as follows:

Category / Program: GENERAL - General Schedule (Code GE)					
MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	*NEW 1* *MP NP*	*2*	*2*	*5*	*Systane*
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses	13100L MP NP	2	2	5	Systane
Restriction Summary 6172 / Treatment of Concept 6172: Authority Required: Streamlined					
Indication: Severe dry eye syndrome					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					

Category / Program: GENERAL - General Schedule (Code GE)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	*NEW 2 OP*	*2*	*2*	*5*	*Systane*
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses	13113E OP	2	2	5	Systane
Restriction Summary 6172 / Treatment of Concept 6172: Authority Required: Streamlined					
Indication: Severe dry eye syndrome					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					

Category / Program: GENERAL - General Schedule (Code GE)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	*NEW 3 MP NP OP 60DAY*	*4*	*4*	*5*	*Systane*
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses	14520F MP NP OP 60DAY	4	4	5	Systane
Restriction Summary 15555 / Treatment of Concept 15555: Authority Required: Streamlined					
Indication: Severe dry eye syndrome					
Clinical criteria:					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					
AND					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					

7.2 Should this item's recommendation proceed at the same time or after item 9.01, add a new medicinal product pack that has <u>28 x 0.8 mL</u> unit doses shown in italics as follows:

Category / Program: GENERAL - General Schedule (Code GE)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					

polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	*NEW 1* *MP OP*	*2*	*2*	*5*	*Systane*
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses	13100L MP ~~NP~~ *OP*	2	2	5	Systane
Restriction Summary [updated number] / ToC [updated number]: Authority Required: Streamlined ***Prescriber types:*** *add optometrists, remove nurse practitioners.*					
Indication: Severe dry eye syndrome					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					
Treatment criteria:					
Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; or					
Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines					

Category / Program: GENERAL - General Schedule (Code GE)					
MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
POLYETHYLENE GLYCOL-400 + PROPYLENE GLYCOL					
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 28 x 0.8 mL unit doses	*NEW 3* *MP OP* *60DAY*	*4*	*4*	*5*	*Systane*
polyethylene glycol-400 0.4% + propylene glycol 0.3% eye drops, 30 x 0.8 mL unit doses	14520F MP ~~NP~~ OP 60DAY	4	4	5	Systane
Restriction Summary [updated number] / ToC [updated number]: Authority Required: Streamlined ***Prescriber types****: remove nurse practitioners*					
Indication: Severe dry eye syndrome					
Clinical criteria:					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					
AND					
Clinical criteria:					
Patient must be sensitive to preservatives in multi-dose eye drops					
Treatment criteria:					
Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist; or					
Must be treated by an optometrist in accordance with Optometry Board of Australia guidelines					

7.3 For administrative simplicity, there will be no optometrist-specific listing as optometrists are able to prescribe under the same PBS item code as ophthalmologists.

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

8 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.

9 Sponsor's Comment

The sponsor had no comment.