

PUBLIC SUMMARY DOCUMENT

Product: TSP (Tamarindus indica seed polysaccharide) Eye Drops, daily dose units, 1%, 0.5 mL, 20, Visine Professional Intensive Dry Eye Daily[®]

Sponsor: Johnson and Johnson Pacific Pty Ltd

Date of PBAC Consideration: July 2007

1. Purpose of Application

The submission sought listing of a new form of eye drops for the treatment of severe dry eyes for people who are sensitive to preservatives.

2. Background

This medical device had not previously been considered by the PBAC.

3. Registration Status

These eye drops are registered as a medical device for the relief of severe dry eyes.

4. Listing Requested and PBAC's View

Authority Required

Severe dry eye syndrome, including Sjogren's syndrome, in patients who are sensitive to preservatives in multi dose eye drops.

The PBAC noted the listing would appear appropriate for inclusion under the streamlined authority arrangements.

5. Clinical Place for the Proposed Therapy

The eye drops are designed to treat severe dry eye syndrome, including Sjogren's syndrome, in patients who are sensitive to preservatives in multi dose eye drops. This syndrome occurs in older people and women who have a reduction in tear fluid in the eye.

6. Comparator

The submission nominated multi dose Cellufresh which contains 5 mg/mL (0.5%) carmellose sodium single dose units as the main comparator.

In the absence of trials comparing TSP with carmellose, the submission provided a clinical comparison with Systane eye drops containing polyethylene glycol 400 with propylene glycol.

7. Clinical Trials

The submission provided details of 4 unpublished and 12 published clinical studies providing support for the efficacy and safety of TSP daily dose units.

The key trials which had been published at the time of submission are as follows:

Trial/First Author	Protocol title	Publication citation
Bonci e et al	The use of a new generation lacrimal substitute in dry eye syndrome	Bollettino di Oculistica Anno 83, N4, 1-11, 2004
Bux AV et al	Comparison between two	Ato Aggiornamenti di Terapia

	artificial tear substitutes in contact lens wearing	Ottalmica 55(1): 4-9 2003.
Lindsay B. et al	A scintigraphic investigation of the precorneal residence time of TS polysaccharide formulations in mild to moderate KCS patients	J Pharm Pharmacol, 54 (supplement) 2002
Mannucci LL. et al	Use of a new lachrymal substitute (TS polysaccharide) in contactology	J Med. Contactology and low vision 1/1:6-9, 2000

8. Results of Trials

These trials support that the eye drop is:

- Long lasting;
- Provides improvement in clinical signs and symptoms of dry eye;
- Compatible with contact lenses ; and
- Has mucomimetic properties.

9. Clinical Claim

The submission claimed that in a comparative trial, Systane and TSP daily dose units were found to have a similar efficacy and safety profile. The submission claimed that TSP daily dose units offers the patient up to 12 drops per day where other single dose units are only reimbursed to 3 doses per day.

The submission also claimed that each vial could be used for up to 12 hours based on a study of microbiological contamination undertaken in Italy.

The PBAC accepted this claim, see Recommendation and Reasons.

10. Economic Analysis

The submission stated that as no efficacy superiority is claimed for TSP daily dose units, no economic evaluation had been undertaken.

11. Estimated PBS Usage and Financial Implications

The number of scripts dispensed was estimated by the submission to be in the range 10,000 – 50,000 in year 4 of listing.

The cost to the PBS was estimated by the submission to be < \$10 million in year 4 of listing. The submission claimed that there may be no additional costs to the PBS if this product replaced other single dose unit dry eye preparations.

12. Recommendation and Reasons

The PBAC recommended the authority required listing of tamarindus indica seed polysaccharide (TSP) on the PBS on a cost-minimisation basis compared with carmellose sodium eye drops (Cellufresh[®]) 5 mg per ml, single dose units. The PBAC noted TSP eye drops contained no preservative and were designed for use over 12 hours, and recommended that the equi-effective doses were 2 units of TSP eye drops daily (24 hours) and 3 units of Cellufresh daily (24 hours).

The PBAC accepted that TSP eye drops were as efficacious and as well tolerated as Systane[®] eye drops (polyethylene glycol 400 with propylene glycol) in the treatment of

severe dry eye syndrome. The Committee also recalled that the listing of all dry eye preparations had been made on the basis of similar efficacy and safety.

The PBAC recommended the listing would be appropriate for listing under the streamlined authority arrangements.

The PBAC recommended the 20 day safety rule should not apply.

Recommendation

TSP (Tamarindus indica seed polysaccharide) Eye Drops, daily dose units, 1%, 0.5 mL, 20

Restriction: Authority required

Severe dry eye syndrome in a patient who is sensitive to preservatives in multi dose eye drops.

Maximum quantity: 3 (x 20)

Repeats: 5

13. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

14. Sponsor's Comment

This summary is an accurate reflection of the application.