

5.21 TACROLIMUS
750 microgram capsule, 100; 2 mg capsule, 100
Tacrolimus Sandoz®,
Sandoz Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested PBS listing of two additional strengths of tacrolimus, 750 microgram and 2 mg. The currently listed strengths are 500 microgram, 1 mg and 5 mg.

2 Requested listing

- 2.1 The submission sought to list the 750 microgram and 2 mg strengths with the same General Schedule and Section 100 Highly Specialised Drugs (public/private) listings as the existing strengths.

For more detail on PBAC's view, see section 6 "PBAC outcome"

3 Background

- 3.1 The currently listed strengths of tacrolimus Sandoz® (a generic version of prograf®) were TGA registered in February 2010 for use as an adjunct to liver, kidney, lung or heart allograft transplantation in adults and children. The two new requested strengths were registered on the ARTG on 25 November 2015.
- 3.2 Tacrolimus was recommended for PBS listing for the prevention of rejection in primary liver transplant recipients at the June 1997 meeting. In September 1999, the listing was extended to include prevention of kidney transplants. The listing was extended again in November 2007 and March 2008 to include cardiac transplants and lung transplants respectively. The current listing for all brands of tacrolimus is management of rejection in patients following organ or tissue transplantation.
- 3.3 The currently listed strengths of tacrolimus sandoz were listed on the PBS on 1 December 2010. The requested strengths have not previously been considered by the PBAC.

4 Clinical place for the proposed therapy

- 4.1 Tacrolimus is an immunosuppressive drug used post-transplant to reduce the risk of organ rejection. Tacrolimus has a narrow therapeutic range and the submission stated that listing of the requested strengths would allow for finer dose adjustment and the ability for a greater number of patients to achieve their target dose.

For more detail on PBAC's view, see section 6 "PBAC outcome"

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 5.3 As a minor submission, no clinical trials were presented in the submission.
- 5.4 The basis of the minor submission's request was changes to the approved Product Information and TGA approval of the 750 microgram and 2 mg strengths. The TGA evaluation report noted that comparative bioequivalence data were not performed as there are no innovator strengths of 750 microgram and 2 mg available. However, noting (among other considerations) that tacrolimus has a narrow therapeutic range; the new strengths fall within the minimum (500 microgram) and maximum (5 mg) strengths already registered and the new strengths are direct scales of existing strengths, the clinical evaluator advised there were no clinical objections to the new strengths.

Economic analysis

- 5.5 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

- 5.6 The minor submission estimated there to be no financial implications to the PBS or the government as the majority of the switch to tacrolimus 750 microgram and 2 mg will occur from an identical priced (per mg) tacrolimus 500 microgram, 1 mg or 5 mg capsule.

For more detail on PBAC's view, see section 6 "PBAC outcome"

6 PBAC outcome

- 6.1 The PBAC recommended listing the additional strengths of tacrolimus, 750 microgram and 2 mg, under the same circumstances and based on a same (ex-manufacturer) price per mg as the currently listed strengths of tacrolimus.
- 6.2 The PBAC accepted that there was a clinical place for the additional strengths, noting that while the addition of the extra strengths may encourage up-titration of patients this was likely to be balanced out with patients who would be down-titrated.
- 6.3 The PBAC noted that the Early Supply Rule currently applies to some of the General Schedule listings of tacrolimus (the 30 packs of the 500 microgram and 5 mg capsules and 60 pack of the 1 mg capsules), but not to the remaining General Schedule listings or any of the Section 100 listings. The PBAC considered that due to significant variation in dosing and the clinical implications of a break in therapy, the Early Supply Rule should not apply to any PBS listing of tacrolimus.
- 6.4 The PBAC recommended that tacrolimus should not be treated as interchangeable on an individual patient basis with any other drug(s) or medicinal formulation(s).
- 6.5 The PBAC advised that tacrolimus is not suitable for prescribing by nurse practitioners.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty (packs)	Max. Qty (units)	No. of Rpts	Proprietary Name and Manufacturer	
TACROLIMUS					
750 microgram capsule	1	100	3	Tacrolimus	Sandoz Pty
2 mg capsule	1	100	3	Sandoz®	Ltd

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
Cautions	Careful monitoring of patients is mandatory

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Name, Restriction, Manner of administration and form	Max. Qty (packs)	Max. Qty (units)	No. of Rpts	Proprietary Name and Manufacturer	
TACROLIMUS					
750 microgram capsule	2	200	5	Tacrolimus	Sandoz Pty
2 mg capsule	2	200	5	Sandoz®	Ltd

Category / Program	Section 100 – Highly Specialised Drugs Program
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Restriction Level / Method:	Authority Required – Private hospitals Streamlined – Public hospitals
PBS Indication:	Management of rejection in patients following organ or tissue transplantation
Clinical criteria:	The treatment must be under the supervision and direction of a transplant unit, AND The treatment must include initiation, stabilisation, and review of therapy as required.
Cautions	Careful monitoring of patients is mandatory

8 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.

9 Sponsor's Comment

The sponsor had no comment.