

5.25 THYROXINE SODIUM 25, 50, 75, 100, 125 and 200 mcg tablets, Eltroxin®, Aspen Pharma Pty Ltd

1 Purpose of application

- 1.1 The submission seeks PBS listing of six strengths of thyroxine sodium (Eltroxin®), including two new strengths not currently listed (25 mcg and 125 mcg).

2 Requested Listing:

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
THYROXINE SODIUM Tablet 25 mcg, 50 mcg, 75 mcg, 100 mcg, 125 mcg, 200 mcg	1	200	1	Eltroxin Aspen Pharma Pty Ltd

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 type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Episodicity:	
Severity:	
Condition:	
PBS Indication:	
Administrative Advice	Note: Eltroxin is not interchangeable with Oroxine/Eutroxsig on a dose to dose basis, and dose titration may be required. Continuing therapy only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicines for, a patient has been initiated by a medical practitioner. Further information can be found in the explanatory notes for nurse practitioners.

3 Background

- 3.1 Thyroxine sodium (also known as levothyroxine sodium) is TGA registered for:
- the management of demonstrated thyroid hormone deficiency,
 - to suppress thyrotropin (TSH) for the management of TSH-responsive tumours of the thyroid.
- 3.2 Two brands of thyroxine sodium are currently PBS listed, Oroxine® and Eutroxsig®. Both these brands are available in 50, 75, 100 and 200 mcg strengths, and are manufactured by the same sponsor (Aspen) in the same facility. Both these brands also require refrigeration.
- 3.3 Eltroxin is manufactured by the same sponsor (Aspen) as the two existing listings of thyroxine sodium, but is made in a different manufacturing facility.
- 3.4 Thyroxine sodium is considered an essential PBS medicine. As such, the listing of thyroxine from a secondary manufacturing facility would be beneficial in ensuring a stable supply of a clinically essential medicine.

4 Suitability for pharmacist substitution

- 4.1 Eltroxin would be listed as a third brand of thyroxine sodium. It is usual practice that, the new listings for the strengths that are already PBS listed would be against the same item codes as the existing listings. The new strengths would be against new item codes.
- 4.2 The PBAC was asked to consider whether Eltroxin is suitable for pharmacist substitution, or should be 'a'-flagged to the existing thyroxine sodium listings, taking into consideration the following TGA and ACPM advice.
- 4.3 It was the TGA delegate's view that while Eltroxin has a different formulation from the reference registered product/s (Oroxine/Eutroxsig) which means that it has increased stability and does not require refrigeration, the trade-off is that it has a different dissolution profile and is less bioavailable.
- 4.4 On the basis of the data provided to the TGA, both the pharmaceutical chemistry evaluator and the clinical evaluator concluded that Eltroxin is not interchangeable with Oroxine/Eutroxsig on a same dose basis.
- 4.5 The TGA delegate, supported by the ACPM, came to the conclusion that Eltroxin is not bioequivalent to Oroxine/Eutroxsig, not interchangeable on a dose by dose basis with Oroxine/Eutroxsig and therefore not a generic equivalent of Oroxine/Eutroxsig.
- 4.6 However, both the TGA delegate and the ACPM were of the view that Eltroxin could be registered as being an alternative to Oroxine/Eutroxsig and that the evidence provided demonstrated that Eltroxin has an overall positive risk-benefit profile for the requested indications, but that the dose would need titrating.
- 4.7 There are precedents of different brands of an item being listed against the same item codes without 'a'-flags. For example, two brands of warfarin 5mg tablets are listed against item code 2211J (Coumadin® and Marevan®), although they are not 'a'-flagged.
- 4.8 The sponsor is not seeking an 'a'-flag for Eltroxin to Oroxine/Eutroxsig.

5 Pricing considerations

5.1 The proposed approved ex-manufacturer price (AEMP) of the Eltroxin brands of thyroxine sodium is [REDACTED] than the current AEMP of the existing listings of Oroxine/Eutroxsig.

5.2 The sponsor has proposed the following prices:

Sponsor proposed prices of thyroxine sodium

	Proposed AEMP	Current AEMP	Current claimed price for Oroxine	Current brand Premium on Oroxine
Thyroxine sodium 25mcg	\$ [REDACTED]	-	-	-
Thyroxine sodium 50mcg	\$ [REDACTED]	\$13.71	\$15.49	\$1.91
Thyroxine sodium 75mcg	\$ [REDACTED]	\$14.23	\$16.07	\$1.98
Thyroxine sodium 100mcg	\$ [REDACTED]	\$14.20	\$15.99	\$1.92
Thyroxine sodium 125mcg	\$ [REDACTED]	-	-	-
Thyroxine sodium 200mcg	\$ [REDACTED]	\$16.65	\$18.44	\$1.93

5.3 Section 85C of the *National Health Act 1953* provides that the AEMP of each listed brand of a pharmaceutical item containing a drug must be the same; “If there are 2 or more listed brands of a pharmaceutical item, then the Minister must ensure, when agreeing an amount under subsection 85AD (1) or determining an amount under subsection 85B (2), that the approved ex-manufacturer price of each listed brand of the pharmaceutical item is the same.”

5.4 This means that the 50, 75, 100 and 200 mcg strengths of Eltroxin must have the same AEMP as the currently listed strengths of Eutroxsig and Oroxine. Although not a matter for the PBAC, it is also noted that in line with current policy, Eltroxin would not be eligible for a brand premium, if there is not an ‘a’-flagged premium free brand available.



6 PBAC consideration of the evidence

Sponsor hearing

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

Consumer hearing

6.2 The PBAC noted that no consumer comments were received this item.

Other relevant factors

6.3 As well as providing an increased assurance of a supply of a clinically essential medicine, the listing of Eltroxin would offer several other potential benefits.

6.4 Eltroxin does not require refrigeration, and can be stored at up to 25 degrees Celsius, which provides another option for patients who are unable to store the current brands of thyroxine sodium at between 2 and 8 degrees Celsius for various reasons.

6.5 The 25 and 125 mcg strengths of Eltroxin may also offer additional single dose treatment options for some patients.

7 PBAC Outcome

7.1 The PBAC noted this medicine is clinically essential and the Eltroxin brand has the benefit of not requiring refrigeration, in ambient temperatures up to 25 degrees Celsius.

7.2 The PBAC noted the Department's advice regarding the pricing of this item.

7.3 The PBAC agreed that the 125 mcg strength may offer additional dosing benefits, but did not agree that the 25 mcg strength was a clinically necessary dose, noting that 50 mcg of thyroxine sodium is the usual therapeutic dose for neonates.

7.4 The PBAC therefore recommended the addition of the 125mcg thyroxine sodium as a new strength as an unrestricted benefit, and the addition of the 50, 75, 100 and 200 mcg strengths as another brand of currently listed strengths.

7.5 The PBAC did not recommend the listing of the 25 mcg strength.

7.6 The PBAC further noted the ACPM and TGA Delegate advice that Eltroxin is not bioequivalent to or interchangeable with the Eutroxig and Oroxine brands on a dose by dose basis and that dose titration may be required for Eltroxin. It recommended that a note be included in the administrative advice of the listing to advise that the brands are not substitutable.

7.7 The PBAC recommended that the Safety Net 20 Day rule should not apply, as is the case for the currently listed products.

7.8 The PBAC recommended that Eltroxin is suitable for prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicines for, a patient has been initiated by a medical practitioner.

Outcome:

Recommended (50, 75, 100, 125 and 200 mcg strengths only)

8 Recommended listing

Add new item:

8.1

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
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9 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.

10 Sponsor’s Comment

All strengths of Eltroxin are available in the market as Private Script items. A submission was lodged to request PBAC to reconsider an unrestricted benefit listing for thyroxine sodium 25 micrograms tablets. This will be considered during March 2016 PBAC meeting.