

6.10 OXYBUTYNIN, Transdermal patches 36 mg, 8 Oxytrol[®], Theramex Australia Pty Ltd

1 Purpose of Submission

- 1.1 The Category 4 submission requested oxybutynin 3.9 mg transdermal patch (Oxytrol[®]) be considered as an exempt item under subsection 84AH of the Act.

2 Background

- 2.1 Oxybutynin 3.9 mg transdermal patch is listed on the PBS as a Restricted Benefit listing for detrusor overactivity in patients unable to tolerate or swallow oral oxybutynin.

Registration status

- 2.2 Oxybutynin 3.9 mg transdermal patch, under the brand name Oxytrol, was first registered by the TGA on 10 May 2007 for the treatment of overactive bladder with symptoms of urinary frequency, urgency or incontinence or any combination of these symptoms.

Previous PBAC consideration

- 2.3 There have been no previous submissions for this type of request in relation to oxybutynin 3.9 mg transdermal patches.

3 Consideration of the evidence

Sponsor hearing

- 3.1 There was no hearing for this item.

Consumer comments

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

Exempt status claim

- 3.3 The submission requested oxybutynin 3.9 mg transdermal patch be determined as an 'exempt item' under subsection 84AH of the Act. Subsection 84AH of the Act provides that the Minister may, by legislative instrument, determine a pharmaceutical item to be an exempt item if:

- (a) there is only one listed brand of the relevant item; and
- (b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and

- (c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and
- (d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:
- i. the listed drug in the relevant item represents suitable therapy for a particular patient population; and
 - ii. the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and
 - iii. no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

3.4 The table below shows the submission’s rationale.

Table 1: Submission rationale for exempt item eligibility

Section 84AH Criteria	Oxytrol (PBS item 9454N)
a) there is only one listed brand of the relevant item; and	There are no other listed brands delivering oxybutynin via a transdermal patch formulation.
b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and	Oxytrol is not ‘a’ flagged to any other PBS listed brands. Ditropan® is the only other listed oxybutynin product. It is a tablet and is not bioequivalent or ‘a’-flagged to the patch.
c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and	The listed brand Ditropan (PBS item code 8039D) is an oral formulation of the same drug, oxybutynin.
d) Advice (if any) given by the Pharmaceutical Benefits Advisory Committee, that:	This submission requested provision/confirmation of such advice:
(i) the listed drug represents suitable therapy for a particular patient population; and	At the March 2009 Meeting, the PBAC recommended the listing of oxybutynin transdermal patches on the PBS for treatment of detrusor overactivity in a patient who cannot tolerate oral oxybutynin or who cannot swallow oral oxybutynin on the basis of acceptable cost effectiveness over placebo.
(ii) the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and	Patients requiring treatment for detrusor overactivity who are unable to tolerate and/or swallow the oral formulation, and unable to afford alternate medicines that are not PBS listed. Detrusor overactivity disproportionately affects Australians over the age of 65 years, and First Nations people over the age of 50 years.
(iii) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.	Oxybutynin, in oral and transdermal forms, is the only medicine available on the PBS for the treatment of overactive bladder (OAB). While there are no other dose forms of oxybutynin available on the PBS for patients unable to tolerate or swallow an oral dose form except for the Oxytrol transdermal patches, the statement that it is the only medicine available on the PBS for this indication is not correct. Propantheline bromide tablets are listed for the treatment of detrusor overactivity, and amitriptyline can also be used for detrusor overactivity.

- 3.5 The submission substantiated its request with clinical data that highlighted the prevalence of Urge Urinary Incontinence (UUI) and chronic conditions in various populations. The data did not demonstrate the clinical benefit provided by the patches over other available dose forms.

4 PBAC Outcome

- 4.1 The PBAC advised that Oxytrol® (oxybutynin 3.9 mg transdermal patch) can be considered as an exempt item under subsection 84AH of the Act.
- 4.2 The PBAC noted that Oxytrol is the only listed brand of oxybutynin for patients for whom the oral formulation is unsuitable due to adverse events or inability to swallow; that there are no bioequivalent, biosimilar or 'a'-flagged products listed for the same indication; and that there is at least one other listed brand of oxybutynin (Ditropan).
- 4.3 The PBAC advised that oxybutynin remains a suitable therapy for the treatment of detrusor overactivity and the transdermal form remains a suitable therapy for patients for whom the oral formulation is unsuitable due to adverse events or inability to swallow. The PBAC advised that there were no other pharmaceutical items containing oxybutynin that were suitable for this patient population as all the alternative therapies are oral dose forms.

Outcome:

Advice provided

5 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.

6 Sponsor's Comment

Theramex wishes to thank the PBAC for their decision.