

14.03(a) CALCIUM

Tablet, chewable, 500 mg (as carbonate), Cal-500[®], Petrus Pharmaceuticals Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a General Schedule (Section 85) Authority Required (STREAMLINED) listing of a new larger pack size of calcium for the treatment of hyperphosphataemia.

2 Requested listing

- 2.1 The minor submission requested the listing of a pack size of 120 tablets, with a maximum quantity of 240 tablets (2 packs) and 1 repeat.
- 2.2 The sponsor sought to replace the currently listed pack size of 60 tablets (4 packs, 1 repeat) with the requested listing. The sponsor advised that it intends to delist the 60 tablet pack size if the 120 tablet pack size is listed.

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
CALCIUM Tablet, chewable, 500 mg, 120	2	240	1	Cal-500 Petrus Pharmaceuticals 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
PBS Indication:	Hyperphosphataemia
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Clinical criteria:	The condition must be associated with chronic renal failure.

3 Background

- 3.1 Cal-500 tablets 60's (AUST L 208475) is listed on the PBS under item number 3116B as an Authority Required (STREAMLINED) listing; and on the RPBS under item numbers 4094L and 4333C as Restricted Benefit listings. For items 4094L and 4333C, the sponsor will need to contact the Department of Veterans' Affairs about these listings if the 60 tablet pack size is delisted.

4 Pricing considerations

- 4.1 The proposed Approved Ex-Manufacturer Price (AEMP) for the 120 tablet pack size is \$■■■■, which is ■■■■■ AEMP of the 60-tablet bottle (\$3.69).
- 4.2 The listing of the 120 tablet pack size is not expected to increase the current market.
- 4.3 There is expected to be no financial impact as a result of the listing of the 120 tablet pack size on the PBS.

5 PBAC Outcome

- 5.1 The PBAC agreed to the listing of a new pack size of 120 for the currently listed pharmaceutical item calcium, tablet, chewable, 500 mg (as carbonate).
- 5.2 The PBAC noted that the sponsor intends to delist the currently listed Cal-500 pack size of 60 tablets once the 120 tablet pack size is listed.

Outcome:

Recommended

6 Recommended listing

- 7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer	
CALCIUM Tablet, chewable, 500 mg, 120	2	240	1	Cal-500	Petrus Pharmaceuticals 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
PBS Indication:	Hyperphosphataemia
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Clinical criteria:	The condition must be associated with chronic renal failure.

7 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.

8 Sponsor's Comment

The sponsor had no comment.