

**6.15 RABEPRAZOLE,
Tablet containing rabeprazole sodium 20 mg
(enteric coated),
Pariet[®],
Janssen-Cilag Pty Ltd**

1 Purpose of Submission

- 1.1 The Committee Secretariat submission sought to request a General Schedule Authority Required (STREAMLINED) PBS/RPBS listing of the existing brand (Pariet[®]) of rabeprazole 20 mg tablets with a new maximum quantity of 28 for its new pack size (hereafter referred to as rabeprazole 20 mg 28-tablet pack) under the same circumstances (apart from the maximum quantity) as the currently listed 20 mg Pariet tablets (hereafter referred to as rabeprazole 20 mg 30-tablet pack).

2 Background

- 2.1 The submission stated that if the Pariet 20 mg 28-tablet pack is PBS-listed the sponsor will request a delisting of the Pariet 20 mg 30-tablet pack.

Registration status

- 2.2 Rabeprazole (Pariet) 20 mg 28-tablet pack was registered in the Australian Register of Therapeutic Goods (ARTG) on 22 June 2020 for the same indications as rabeprazole 20 mg 30-tablet pack.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Requested listing

- 3.1 The submission requested the following new listing and did not propose any changes to the existing restrictions.

Add new medicinal product pack as follows:

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MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
<i>RABEPRAZOLE</i>					
<i>rabeprazole sodium 20 mg enteric tablet, 28</i>	<i>NEW</i>	<i>1</i>	<i>28</i>	<i>5</i>	<i>Pariet</i>
<i>rabeprazole sodium 20 mg enteric tablet, 28</i>	<i>NEW</i>	<i>1</i>	<i>28</i>	<i>1</i>	<i>Pariet</i>
<i>rabeprazole sodium 20 mg enteric tablet, 28</i>	<i>NEW</i>	<i>2</i>	<i>56</i>	<i>1</i>	<i>Pariet</i>
rabeprazole sodium 20 mg enteric tablet, 30	11670F	1	30	5	APO- Rabeprazole® Parbezol® Rabeprazole Mylan® Rabeprazole SUN® Rabeprazole® Sandoz® Zabep® Pariet
rabeprazole sodium 20 mg enteric tablet, 30	12286P	2	60	5	APO-Rabeprazole Parbezol Rabeprazole Mylan Rabeprazole SUN Rabeprazole Sandoz Zabep Pariet
rabeprazole sodium 20 mg enteric tablet, 30	8508T	1	30	5	APO-Rabeprazole Parbezol Rabeprazole Mylan Rabeprazole SUN Rabeprazole Sandoz Zabep Pariet
rabeprazole sodium 20 mg enteric tablet, 30	8509W	1	30	1	APO-Rabeprazole Parbezol Rabeprazole Mylan Rabeprazole SUN Rabeprazole Sandoz Zabep Pariet
rabeprazole sodium 10 mg enteric tablet, 28	8507R	1	28	5	APO-Rabeprazole Parbezol Rabeprazole Sandoz Pariet

3.2 The requested maximum quantity for rabeprazole 20 mg 28-tablet pack is different from the other existing brands of rabeprazole 20 mg 30-tablet pack for the same indications, which have a maximum quantity of 30 tablets. The following recommended oral doses for adults are included in the Pariet tablets Product Information:

- gastro-oesophageal reflux disease (GORD): one 20 mg tablet once daily for four to eight weeks.
- prevention of relapse of GORD: 10 mg once daily once healing is achieved. If needed this dose should be increased to 20 mg once daily.
- symptomatic treatment of GORD: initially 10 mg once daily in patients without oesophagitis. If no response, the dose should be increased to 20 mg once daily for four weeks.
- treatment of active duodenal or gastric ulcer: 20 mg once daily. Most patients with active duodenal ulcer heal within four weeks (a few patients may require an additional four weeks of treatment to achieve healing). Most patients with gastric ulcer heal within six weeks (a few patients may require an additional six weeks of treatment to achieve healing).

Rabeprazole 20 mg 28-tablet pack size provides sufficient treatment to complete short term treatment courses (4-8 weeks).

3.3 The Secretariat noted it will not be possible for rabeprazole 20 mg 28-tablet pack and rabeprazole 20 mg 30-tablet pack to be considered equivalent for the purpose of substitution at the pharmacy level ('a'-flagged) due to the different maximum quantities. This is due to State and Territory legislation that prevents pharmacists from dispensing a quantity that is different from what was prescribed.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The Pharmaceutical Benefits Advisory Committee (PBAC) noted that no consumer comments were received for this item.

Pricing considerations

4.3 The submission proposed an approved ex-manufacturer price (AEMP) of \$2.83 for rabeprazole 20 mg 28-tablet pack. This is the same AEMP as rabeprazole 20 mg in the 30-tablet pack. Under section 85D of the *National Health Act 1953* the AEMP of

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different pack sizes must be proportional, therefore the appropriate AEMP for the 28-tablet pack is \$2.64.

- 4.4 The submission stated that the Pariet brand of rabeprazole 20 mg in the 30-tablet pack is subject to a brand premium. It is not possible to apply a brand premium to the 28-tablet pack, where it is not substitutable with any other brands, due to the difference in maximum quantity (see paragraph 3.3). This is not a matter for the PBAC.
- 4.5 The submission stated that a PBS-listing of rabeprazole 20 mg 28-tablet pack at the requested AEMP (same as rabeprazole 30-tablet pack) is expected to result in a small cost to the PBS/RPBS. This is set out in Tables 1 and 2 which were provided in the submission. They present the estimated extent of use of rabeprazole 20 mg 28-tablet pack over rabeprazole 20 mg 30-tablet pack, cost of Pariet 20 mg 28-tablet pack and the net financial impact of listing.

Table 1. Estimated net effect of listing Pariet® 20 mg, 28-tablet pack on script volume

Year	2022	2023	2024	2025	2026	2027
Script volume of rabeprazole sodium 20 mg, 30-tablet pack	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹	█ ¹
Annual rate of growth		-1.33%	-1.17%	-1.05%	-0.95%	-0.87%
Brand share of Pariet® 20 mg, 30-tablet pack	20.95%	20.56%	20.23%	19.93%	19.68%	19.45%
Number of Pariet® 20 mg, 30-tablet packs in the absence of the 28-tablet pack	█ ²	█ ²	█ ²	█ ⁶	█ ⁶	█ ⁶
Percentage of Pariet® 20 mg 30-tablet pack replaced by the 28-tablet pack	50%	100%	100%	100%	100%	100%
Number of Pariet® 20 mg 28-tablet packs based on script equivalence of one 30-tablet pack = 1.07 28-tablet packs	█ ³	█ ²	█ ²	█ ²	█ ²	█ ²
Net increase in script volume for Pariet® 20 mg	█ ⁴	█ ⁵	█ ⁵	█ ⁵	█ ⁵	█ ⁴

Source: Submission letter, page 5

The redacted values correspond to the following ranges:

¹ 1,000,000 to < 2,000,000

² 300,000 to < 400,000

³ 100,000 to < 200,000

⁴ 10,000 to < 20,000¹

⁵ 20,000 to < 30,000

⁶ 200,000 to < 300,000

Table 2. Net financial impact of Pariet® 20 mg, 28-tablet pack on health budget

Cost to the PBS/RPBS	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
	2022	2023	2024	2025	2026	2027
PBS						
New listing (\$)	¹	¹	¹	¹	¹	¹
Changed listing (\$)	- ²	- ²	- ²	- ²	- ²	- ²
Net cost to the PBS (\$)	¹	¹	¹	¹	¹	¹
RPBS						
New listing (\$)	¹	¹	¹	¹	¹	¹
Changed listing (\$)	- ²	- ²	- ²	- ²	- ²	- ²
Net cost to the RPBS (\$)	¹	¹	¹	¹	¹	¹
PBS + RPBS						
Net cost to the PBS/RPBS (\$)	¹	¹	¹	¹	¹	¹

Source: Submission letter, page 4

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

4.6 The submission claimed that the cost of rabeprazole 20 mg 28-tablet pack to the PBS/RPBS is expected to be \$10 to < \$20 million over six years (Year 1 \$0 to < \$10 million per year to Year 6 \$0 to < \$10 million per year).

4.7 The submission claimed that this listing is expected to have an impact of net cost saving on the utilisation of existing PBS/RPBS listings of rabeprazole 20 mg 30-tablet pack over six years.

4.8 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of rabeprazole 20 mg 28-tablet pack is \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million per year to Year 6 \$0 to < \$10 million per year). The estimated cost proposed by the sponsor was based on an AEMP of \$2.83.

4.9 As a Committee Secretariat submission, the financial estimates have not been independently evaluated.

For more detail on PBAC’s view, see section 5 PBAC outcome.

5 PBAC Outcome

5.1 The PBAC recommended the listing of rabeprazole 20 mg 28-tablet pack with a maximum quantity of 28 tablets.

5.2 The PBAC noted the pre-PBAC response proposed listing rabeprazole 20 mg 28-tablet pack with a maximum quantity of 30. The PBAC did not consider this request appropriate because of the potential wastage caused by breaking a 28 pack of rabeprazole to make up the quantity of 30.

5.3 The PBAC advised that in the Schedule of Pharmaceutical Benefits, rabeprazole 20 mg 28-tablet pack and rabeprazole 20 mg 30-tablet pack should not be treated as

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equivalent ('a'-flagged) to each other for the purposes of substitution, due to the different maximum quantities between the requested listing and the existing listing.

- 5.4 The PBAC noted that under section 85D of the Act the AEMP of the 28-tablet pack should be proportional and noted at the time of consideration the appropriate AEMP for the 28-tablet pack is \$2.64.
- 5.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because rabeprazole 20 mg 28-tablet pack is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over other currently listed rabeprazole 20 mg 30-tablet packs, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 5.6 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new item:

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This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 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.

8 Sponsor's Comment

The sponsor had no comment.