

5.21 MESALAZINE

Tablet 1 g (enteric coated), Salofalk[®], Orphan Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested an Authority Required (STREAMLINED) listing for a new strength of mesalazine enteric-coated tablet for the treatment of ulcerative colitis and Crohn disease.

2 Requested listing

- 2.1 The submission sought the same restrictions as the current PBS listings for mesalazine 250 mg and 500 mg enteric-coated tablets.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
MESALAZINE mesalazine 1 g enteric tablet, 60	2	5	\$ [REDACTED]	Salofalk [®] Orphan Australia 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:	Ulcerative colitis
Restriction Level/Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have had a documented hypersensitivity reaction to a sulphonamide, OR Patient must be intolerant to sulfasalazine.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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:	Crohn disease
Restriction Level/Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have had a documented hypersensitivity reaction to a sulphonamide, OR Patient must be intolerant to sulfasalazine.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

*The DPMQ of mesalazine 1 g modified release tablet changed on 1 June 2018, when a 10% and 5% anniversary price reduction was applied to mesalazine as it had been listed on the PBS for 10 and 15 years.

3 Background

- 3.1 Mesalazine has been registered with the TGA since 6 April 1994. Mesalazine 1 g enteric-coated tablet was TGA registered on 16 January 2018.
- 3.2 There are 18 forms of mesalazine currently listed on the PBS. The PBAC most recently considered mesalazine at its March 2017 meeting, when it recommended the listing of 800 mg enteric-coated tablets for the treatment of ulcerative colitis.

For more detail on PBAC’s view, see section 6 PBAC outcome.

4 Comparator

- 4.1 As this was a minor submission, there was no economic comparison. The minor submission nominated Pentasa 1 g modified release tablet as the main price comparator. The submission indicated that mesalazine 1 g enteric-coated tablets would substitute for Mezavant 1.2 g modified release tablets, Pentasa 1 g modified release tablets, Salofalk 500 mg enteric-coated tablets and, to a smaller extent, Mesasal 250 mg enteric-coated tablets in clinical practice.

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 this was a minor submission, no new clinical trials were presented. However, the submission noted the TGA's acknowledgement that in clinical trials submitted by the sponsor, 88.2% of patients either preferred a single 1 g tablet to two 500 mg tablets, or were indifferent between the two options.
- 5.4 The minor submission claimed that listing the 1 g enteric-coated tablets would increase patient compliance in the long term due to reduced pill burden for some patients. This claim was not supported by any direct evidence in the submission. The pre-PBAC response referenced a publication which identified 'high number of pills/drugs' as a barrier to medication adherence/compliance¹. The PBAC considered that the claim of increased compliance was not a relevant consideration in its decision whether to recommend the listing of mesalazine 1 g enteric-coated tablets as this claim was not factored into the proposed price.

Estimated PBS usage & financial implications

- 5.5 The minor submission proposed the same ex-manufacturer price as the currently listed Pentasa 1 g modified release tablet (\$135.50 at the time of submission). The approved ex-manufacturer price of Pentasa 1 g modified release tablet since 1 June 2018 is \$115.68 due to the application of a 5% and 10% anniversary price reduction to mesalazine on this date for 15 and 10 years of being listed on the PBS. The sponsor acknowledged this price change and indicated acceptance of the new price in its pre-PBAC response.
- 5.6 The minor submission estimated a net save to the PBS and RPBS of \$ [REDACTED] in Year 5 of listing, with a total net save of \$ [REDACTED] over the first 5 years of listing. This is summarised in the table below along with expected prescription numbers. The Department has not evaluated the utilisation and financial estimates presented in the submission.
- 5.7 The estimated savings reflect the claim in the minor submission that mesalazine 1 g enteric-coated tablets will be a substitute for other forms of mesalazine currently listed on the PBS that are more expensive per gram (e.g. Salofalk 500 mg enteric-coated tablets).

¹ Kane, S V (2007). *Patient Adherence in Inflammatory Bowel Disease*. Gastroenterology & Endoscopy News Special Edition

Table 1: Estimated cost to the PBS/RPBS

	Year 1	Year 2	Year 3	Year 4	Year 5	Years 1-5 Cumulative
Script volumes						
PBS						
RPBS						
Total script volume						
Net Cost of listing						
PBS	\$	\$	\$	\$	\$	\$
RPBS	\$	\$	\$	\$	\$	\$
Total net cost of listing	\$	\$	\$	\$	\$	\$
Net cost of displaced scripts						
PBS	\$	\$	\$	\$	\$	\$
RPBS	\$	\$	\$	\$	\$	\$
Total cost of displaced scripts	\$	\$	\$	\$	\$	\$
Overall cost to PBS/RPBS						
Overall cost to PBS	\$	\$	\$	\$	\$	\$
Overall cost to RPBS	\$	\$	\$	\$	\$	\$
Total overall cost	\$	\$	\$	\$	\$	\$

Source: Mesalazine (Salofalk) 1g ec tablet Utilisation-and-Cost-Model Spreadsheets.xlsx

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required (STREAMLINED) listing of mesalazine 1 g enteric-coated tablets for the treatment of ulcerative colitis and Crohn disease on a cost-minimisation basis against the oral formulation of mesalazine on the PBS with the lowest price per milligram of mesalazine.
- 6.2 The PBAC noted that the 1 g enteric-coated tablets would reduce the pill burden for some patients.
- 6.3 The PBAC noted that listing of the 1 g enteric-coated tablet form of mesalazine is unlikely to increase the overall utilisation of PBS listed mesalazine. The PBAC advised that the Early Supply Rule should apply to this form of mesalazine, as it applies to all other PBS-listed forms.
- 6.4 The PBAC advised that this form of mesalazine is suitable for prescribing by nurse practitioners as continuing therapy within a shared care model only.
- 6.5 The PBAC noted that this submission would not meet the criteria for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
MESALAZINE mesalazine 1 g enteric tablet, 60	2	5	Salofalk®	Orphan Australia 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:	Ulcerative colitis
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have had a documented hypersensitivity reaction to a sulphonamide, OR Patient must be intolerant to sulfasalazine.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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:	Crohn disease
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Clinical criteria:	Patient must have had a documented hypersensitivity reaction to a sulphonamide, OR Patient must be intolerant to sulfasalazine.
Administrative Advice	Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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.