

## 5.19 MESALAZINE

### **3 g granules: modified release, 30 sachets; Salofalk®; Orphan Australia Pty Ltd.**

#### **1 Purpose of Application**

- 1.1 The minor submission requested listing of a new, higher strength of mesalazine granules for the same Authority Required (STREAMLINED) listing as the existing 500 mg, 1 g and 1.5 g Salofalk® branded sachets in the treatment of ulcerative colitis where hypersensitivity to sulphonamides exists or where intolerance to sulfasalazine exists.

#### **2 Background**

- 2.1 Mesalazine was TGA registered on 2 July 2014 for the treatment of acute ulcerative colitis of mild to moderate severity, and for the maintenance of remission and/or the long term treatment of ulcerative colitis.
- 2.2 In March 2002, mesalazine granules (500 mg and 1 g sachets) were recommended for listing on the basis of the price being acceptable relative to mesalazine tablet 250 mg, on a mg for mg basis.
- 2.3 In July 2008, the PBAC recommended out of session an Authority Required (STREAMLINED) listing of a new strength (1.5 g sachets) of mesalazine granules for the treatment of ulcerative colitis in a patient who meets certain criteria. The PBAC noted the sponsor's advice that the new strength would provide patients with the option of a once daily dosage.

#### **3 Requested listing**

- 3.1 The minor submission did not request any changes to the existing restrictions. The restrictions applying to the corresponding, currently listed strengths of Salofalk are shown below:

Authority Required (STREAMLINED)

1708

Ulcerative colitis where hypersensitivity to sulfonamides exists

Authority Required (STREAMLINED)

1709

Ulcerative colitis where intolerance to sulfasalazine exists

Note

Not for the treatment of Crohn disease.

Note

Continuing Therapy Only:

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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.

- 3.2 The proposed maximum quantity (packs) was 1 (which equated to 30 units) and the number of repeats was 5.
- 3.3 The proposed dispensed price for maximum quantity was \$267.18. It was noted that this price was higher than that applying to the existing 1.5 g granules (\$245.26) and was justified by the minor submission by the assumption that the new 3 g granules would substitute for a mix of 1 g and 1.5 g Salofalk branded granules (and to a smaller extent, Pentasa branded granules) and therefore the price of \$267.18 reflected a weighted mix of these various products and strengths.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

### **4 Clinical place of the proposed therapy**

- 4.1 Mesalazine granules are currently listed on the PBS come in various strengths, i.e. 500 mg, 1 g, 1.5 g and 2 g preparation. The approved Product Information states that for acute treatment, the recommended dose is 1.5 g – 3 g daily either as a single dose or in divided doses. The new 3 g sachet presentation would offer an alternative for patients currently taking 2 x 1.5 g sachets or 3 x 1 g sachets to achieve a daily dose of 3 g for acute treatment.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

### **5 Comparator**

- 5.1 The minor submission did not formally nominate a comparator but based on the minor submission's PBS usage and financial estimates, 1.5 g Salofalk<sup>®</sup> is the therapy the minor submission assumed that the new 3 g presentation would replace the most.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

### **6 Consideration of the evidence**

#### **Clinical trials**

- 6.1 As a minor submission, no clinical trials were presented in the submission.

#### **Clinical claim**

- 6.2 The submission stated that listing of a 3 g preparation would allow convenience for patients requiring a dose of 3 g for acute treatment.

## Economic analysis

6.3 As a minor submission, a formal economic comparison was not presented.

## Estimated PBS usage & financial implications

6.4 The minor submission claimed that there would be no increase in market usage of mesalazine granules as the listing of the 3 g mesalazine would directly substitute for the 1 g, 1.5 g Salofalk<sup>®</sup> products and some 1 g and 2 g Pentasa<sup>®</sup> products. The submission further claimed that there would be a net savings of approximately \$300,000 over 5 years as a result of direct substitution with other presentations.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

## 7 PBAC Outcome

7.1 The PBAC recommended the listing of mesalazine 3 g granules as an Authority required (Streamlined) benefit for the treatment of ulcerative colitis where hypersensitivity to sulphonamides exists or where intolerance to sulfasalazine exists, on a cost-minimisation basis with the 1.5 g granules of Salofalk.

7.2 The PBAC considered that patients requiring a mesalazine once daily dose of 3 g would be likely to be those already prescribed the 1.5 g sachets and therefore, if the new 3 g sachets (30 sachets) were equivalently priced to the 1.5 g sachets (60 sachets), there would be minimal net financial implications of listing the new 3 g sachets.

7.3 The PBAC recommended that the Safety Net 20 Day rule should apply as it is currently applied to the existing mesalazine oral formulations.

7.4 The PBAC recommended that mesalazine 3 g should be included in the list of medicines for prescribing by nurse practitioners for continuing therapy only.

### Outcome:

Recommended

## 8 Recommended listing

8.1 Add new item (shown in ***bolded italics***):

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Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
<b>MESALAZINE</b>				
mesalazine 500 mg granules, 100 x 500 mg sachets	2	100	5	Salofalk OA
mesalazine 1 g granules: modified release, 100 x 1 g sachets	1	100	5	Salofalk OA
mesalazine 1.2 g tablet: modified release, 60 tablets	1	60	5	Mezavant ZI
mesalazine 1.5 granules, 60 x 1.5 g sachets	1	60	5	Salofalk OA
<b>mesalazine 3 g granules: modified release, 30 x 3 g sachets</b>	<b>1</b>	<b>30</b>	<b>5</b>	<b>Salofalk OA</b>

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	---
<b>Severity:</b>	---
<b>Condition:</b>	Ulcerative colitis
<b>PBS Indication:</b>	Ulcerative colitis ( <i>Streamlined code to be announced</i> )
<b>Treatment phase:</b>	----
<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR Patient must be intolerant of sulfasalazine
<b>Administrative Advice</b>	<u>NOTE:</u> Not for the treatment of Crohn disease  <u>NOTE:</u> 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.

## 6 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

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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.

**7 Sponsor's Comment**

The Sponsor had no comment.