

6.17 MESALAZINE
Modified released, 1.2 g tablet, 60
Mezavant®, Shire.

1 Purpose of Application

1.1 The minor submission sought to increase the current maximum quantity from 1 pack of 60 tablets to 2 packs of 60 tablets for mesalazine 1.2g modified released tablets for the treatment of ulcerative colitis (UC).

2 Requested listing

2.1 The submission requested an increase in maximum quantity and did not request changes made to the current number of repeats and the restriction wording for UC.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
MESALAZINE Modified released tablets, 1.2 g	4 2	5	\$ [REDACTED]*	Mezavant® Shire

*: Tier 2 AHI fee included

3 Background

3.1 At its November 2009 meeting, the PBAC recommended a listing of mesalazine 1.2 g prolonged release tablets on the PBS as an authority required (streamlined) benefit for the treatment of ulcerative colitis where hypersensitivity to sulfonamides or intolerance to sulfasalazine exists on a cost minimisation basis with Salofalk® and Pentasa® brands of mesalazine at the same price per mg of mesalazine. The PBAC noted that mesalazine 1.2 g prolonged release tablets are a higher strength tablet recommended for once daily administration which will provide an additional strength of mesalazine on the PBS and a reduced tablet burden.

4 Summary of Submission

4.1 The submission stated that since doses required for induction and maintenance of remission of UC range from 2.4 - 4.8g/day, the current maximum quantity of 60 tablets are not sufficient for patients who require a higher dose of 4.8g/day. Therefore, a maximum quantity of 120 tablets would provide sufficient supply for one month for patients who require a higher dose.

4.2 The submission also stated that the increased maximum quantity would be consistent with other mesalazine products (Pentasa® 500mg and 1g modified released tablets, Salofalk® 500 mg enteric tablets).

4.3 The submission stated that the increased maximum quantity would reduce financial burden for the patients and reduce administrative burden for doctors.

5 PBAC 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 The submission presented an analysis of the PBS 10% sample conducted by Propection Ltd to support its claim of a high proportion of patients (59%) using larger doses and an increase in frequency of doctors applying for authorities for a larger maximum quantity of Mezavant.

5.4 The analysis showed an increase in authority applications for larger quantities of Mezavant.

Estimated PBS usage & financial implications

5.5 The submission requested the same price per mg (ex-man) as the 1x60 tablets. The submission stated that the price of Mezavant is based on the current prices, and a 5% decrease to the ex-manufacturer price from April 2016 is included.

5.6 The minor submission used a market share approach to estimate utilisation and financial costs for the requested change. The submission assumed that a small proportion of the market would continue to be prescribed 1 pack of 60 tablets (2.4 g/day), which was reflected in the projected market.

5.7 The submission stated that Mezavant would not be substituted for other mesalazine products as they are not considered interchangeable due to differences in formulation. Therefore, there would be no growth in the market as a result of the increased maximum quantity.

5.8 The minor submission estimated a net cost increase to the PBS of \$ [REDACTED] *less than \$10 million* in Year 5 of listing, with an assumption that 90% market share would be held by the new maximum quantity (2x60 tablets) and 10% would be held by the maximum quantity of 1x60 tablets. The costing has not been verified. The submission also estimated that a total net save to patient co-payments of \$ [REDACTED] over the first 5 years of listing.

5.9 The submission also presented sensitivity analyses, which showed that a net increase to the PBS of \$ [REDACTED] (assumption of 70% prescriptions for 2x60 tablets and 30% for 1x60 tablets) and \$ [REDACTED] (100% prescriptions for 2x60 tablets) in Year 5 of listing.

6 PBAC Outcome

- 6.1 The PBAC recommended an increase in maximum quantity to 2 packs of 60 tablets for mesalazine 1.2 g modified released tablets (Mezavant) for the treatment of ulcerative colitis (UC).
- 6.2 The PBAC noted an utilisation analysis of Mezavant for UC prepared by the DUSC Secretariat showed that from October 2013 to September 2014, 46% of patients were identified as being dispensed with a higher dose on average. The proportion of patients increased to 50.3% between May 2014 to April 2015. This was consistent with the submission's claim of an increasing proportion of patients being on a higher dose. The PBAC considered that it is reasonable that the maximum quantity be changed from 1x60 tablets to 2x60 tablets.
- 6.3 The PBAC accepted the submission's request for the same price per mg (ex-man) noting that this methodology has been accepted for other items in this class. However PBAC considered that there may be grounds to confirm the cost effectiveness of use at higher doses, and asked that Department consider this in any future Post Market Reviews of colitis treatments.

Outcome:

Recommended

7 Recommended listing

Amend maximum quantity as follows:

Authority Required (STREAMLINED)

4824

Ulcerative colitis

Clinical criteria:

Patient must have had a documented hypersensitivity reaction to a sulphonamide; OR

Patient must be intolerant to sulfasalazine.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Manufacturer	Name and
MESALAZINE				
Modified released tablets, 1.2 g, 60 tablets	4 2	5	Mezavant®	Shire

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

Shire welcomes the PBAC recommendation to amend the listing for Mezavant® (mesalazine) for patients with ulcerative colitis.