

14.03 AURANOFIN

Tablet, 3 mg, 100

Ridaura®, Amdipharm Mercury Pty. Ltd.

1 Purpose of Application

- 1.1 The submission requested the addition of a maximum quantity of 100 to the current auranofin listing to accommodate supply of the 100 tablet pack to address a shortage of the pack of 60 tablets.

2 Requested Listing

- 2.1 The submission requested the listing under the same conditions as the current listing for auranofin 3 mg, with an increase in maximum quantity to 100. This is an unrestricted benefit.

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

3 Background

- 3.1 The 100 tablet pack of auranofin 3 mg is not currently on the ARTG, however the sponsor has been granted s19A approval. This approval is only valid to 31 December 2016

4 Consideration of the evidence

Estimated PBS usage & financial implications

- 4.1 Based on the recommended dose of two tablets per day, the 100 tablet pack will provide 20 extra days of treatment. The financial impact of this due to a reduction in the number of patient co-payments will be negligible (less than \$10 million per year), noting that the sponsor currently only has s19A approval until 31 December 2016.

5 PBAC outcome

- 5.1 The PBAC recommended the addition of a maximum quantity of 100 to the current auranofin 3mg listing, on the same price per tablet (AEMP) basis as the 60 pack, and under the same listing conditions as the auranofin 3 mg, 60 tablet pack.
- 5.2 The PBAC noted the small population using auranofin, and the significant changes in treatment since its listing. They considered that it may be necessary to review the place in therapy of auranofin in the treatment of rheumatoid arthritis, and that advice should be sought from the Australian Rheumatology Association.

Outcome:

Recommended

6 Recommended listing

6.1 New listing

Name, Restriction, Manner of administration and form	Max. Qty (Packs)	Max. Qty (Units)	No. of Rpts	Proprietary Name and Manufacturer
AURANOFIN Tablet 3 mg	1	100	3	Ridaura® Amdipharm Mercury

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
Caution:	Regular blood and urine checks are essential.
Administrative advice	Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

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.