

6.10 FEBUXOSTAT

Tablet 80 mg,

Adenuric[®], A.Menarini Australia Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested to amend the current Authority Required listing to Authority Required (Streamlined) for treatment of chronic gout.

2 Requested listing

- 2.1 The submission requested change in the restriction level of the existing listing from Authority Required to Authority Required (Streamlined), but no other changes to the existing listing.

3 Background

- 3.1 Febuxostat was TGA registered for the treatment of symptomatic hyperuricaemia in conditions where urate deposition has already occurred (gouty arthritis and/or tophus formation) in adults with gout on 18 December 2014.
- 3.2 The PBAC recalled that it previously recommended the listing of febuxostat as an Authority Required benefit for patients with a contraindication to, or intolerant of treatment with allopurinol at the March 2015 meeting. The PBAC recommendation was on the basis of a clinical need for an alternative second-line treatment to probenecid (the comparator) in this patient population (Public Summary Document, March 2015 PBAC meeting).
- 3.3 The PBAC recalled that its previous recommendation for an Authority Required listing and not an Authority Required (STREAMLINED) was to address concerns about use of febuxostat in the first line setting (Public Summary Document, March 2015 PBAC meeting).
- 3.4 The PBAC noted that a Risk Sharing Agreement was in place to reduce the risk of unexpected Commonwealth expenditure on febuxostat if used beyond the recommended listing (Public Summary Document, March 2015 PBAC meeting). The risk sharing agreement expenditure cap to be calculated based on the conservative estimate that up to ■%of patients with chronic gout cannot take allopurinol for reasons relating to contraindications or adverse effects.

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 as it was a minor submission.

Consumer comments

4.2 The PBAC noted that no consumer comments were received for this item.

Estimated PBS usage & financial implications

4.3 The minor submission estimated there to be no financial implications to the PBS as the current risk sharing arrangement provides surety of overall PBS expenditure.

4.4 The sponsor claimed that a change on the restriction level would not increase the use of febuxostat in an ineligible patient population but allow easier access to the previously recommended population.

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

5 PBAC Outcome

5.1 The PBAC did not recommend amending the current Authority Required listing of febuxostat to Authority Required (STREAMLINED) for treatment of chronic gout.

5.2 The Sponsor presented the utilisation of febuxostat in the first 18 months of listing, and claimed that the number of scripts used was lower than anticipated. The sponsor assumed that the current lower than expected utilisation of the drug was due to the Authority Required restriction.

5.3 However, the PBAC did not consider that the Authority Required restriction necessarily presented a solely administrative barrier for prescribers (ie it may be also sending a useful signal regarding appropriate prescribing)

5.4 The PBAC noted that the decision to list febuxostat as an Authority Required benefit and not as an Authority Required (STREAMLINED) benefit was in part due to the risk that febuxostat may have been prescribed inappropriately in allopurinol insufficient patients.

5.5 The PBAC recalled its concern that there was the paucity of evidence of efficacy and safety of febuxostat in allopurinol insufficient patients. Therefore, the request to list

febuxostat in allopurinol insufficient patients was not adequately supported by the evidence available to the Committee (Public Summary Document, March 2015 PBAC meeting). The use of febuxostat in these patients was not addressed in the current submission.

- 5.6 The pre-PBAC response argued that the risk of leakage was addressed by the Risk Sharing Agreement, and the subsidisation caps were calculated based on the estimated population of allopurinol intolerant patients; i.e. excluding allopurinol insufficient patients.
- 5.7 However, the PBAC considered the previous concerns remained and that the Authority Required restriction remained appropriate to prevent the risk of prescribing behaviour outside of the current PBS restriction. While the utilisation is lower than anticipated, the PBAC was of the view that the current utilisation data could also suggest that the restriction is effectively targeting treatment to the right patient group. The PBAC recalled that from March 2015 PBAC meeting, it had recommended that DUSC should review febuxostat usage at an appropriate time after listing. The PBAC reconfirmed this request and recommended that the utilisation and restriction level of febuxostat should be revisited after a DUSC review in twelve months' time.
- 5.8 The PBAC noted that this submission is not eligible for an Independent Review as an Independent Review is not available in response to a request to modify an existing listing.

Outcome:

Rejected

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 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

Public Summary Document – July 2017 PBAC Meeting

A.Menarini remains committed to working with the PBAC to streamline access to febuxostat for all patients who qualify under the previously agreed clinical criteria.