

## 5.16 ITRACONAZOLE 50 mg capsule, 60; Lozanoc<sup>®</sup>; Mayne Pharma International Ltd.

### 1 Purpose of Application

- 1.1 Authority Required (STREAMLINED) listing of itraconazole 50 mg capsule (Lozanoc<sup>®</sup>) for the same indications as the currently PBS-listed itraconazole 100 mg capsule (Sporanox<sup>®</sup>).

### 2 Requested listing

- 2.1 The submission sought the following new listing, in line with the price and indications of the current PBS-listing for itraconazole 100 mg.

### 3 Background

- 3.1 Itraconazole 50 mg capsule (Lozanoc<sup>®</sup>) is TGA registered for the following indications:

#### Superficial mycoses

Lozanoc<sup>®</sup> is indicated if external treatment is not effective or not appropriate, for the treatment of the following fungal infections: dermatomycoses (e.g. *tinea corporis*, *tinea cruris*, *tinea pedis*, *tinea manus*, *tinea unguium*) and *Pityriasis versicolour*.

#### Systemic mycoses

Lozanoc<sup>®</sup> is indicated for the treatment of systemic mycoses, such as *candidiasis*, *aspergillosis*, and *histoplasmosis*.

Consideration should be given to official guidance on the appropriate use of antimycotic agents, and to the discussion of the pharmacodynamics properties (see PHARMACOLOGY).

- 3.2 Lozanoc<sup>®</sup> had not been considered by PBAC previously.

### 4 Clinical place for the proposed therapy

- 4.1 Lozanoc<sup>®</sup> is TGA approved for superficial and systemic mycoses indications. This minor application requested listing for systemic mycoses only, as per the current PBS-listing for itraconazole 100 mg (Sporanox<sup>®</sup>).
- 4.2 One 50 mg capsule of itraconazole (Lozanoc<sup>®</sup>) has a higher bioavailability than other itraconazole capsules and is therapeutically equivalent to one 100 mg capsule of itraconazole. However, Lozanoc<sup>®</sup> and itraconazole 100 mg are not considered interchangeable.

*For more detail on PBAC’s view, see section 6 “PBAC outcome”*

## **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 As a minor submission, no clinical trials were presented in the submission.

5.4 The TGA delegate, on the basis of advice from the ACPM, initially only approved Lozanoc<sup>®</sup> for the treatment of superficial mycoses with dosing restricted to the fasting state. The applicant appealed this decision and the TGA appeal delegate subsequently revoked the initial decision and substituted their own decision to approve “Lozanoc 50 mg capsules, fasted and fed, for the treatment of superficial and systemic mycoses...”. In the reasons for this decision, the appeal delegate “found evidence to support the arguments of Mayne Pharma concerning the therapeutic equivalence of Lozanoc 50 mg capsules, both fed and fasted, to the marketed product Sporanox, 100 mg, included for the management of both superficial and systemic mycoses”.

*For more detail on PBAC’s view, see section 6 “PBAC outcome”*

### **Estimated PBS usage & financial implications**

5.5 The submission requested the same price as the currently listed itraconazole 100 mg for the same systemic mycoses indications. This approach is reasonable on the basis of the TGA appeal delegate’s conclusion of the therapeutic equivalence of Lozanoc<sup>®</sup> 50 mg capsules and Sporanox<sup>®</sup> 100 mg.

5.6 The minor submission did not address estimated PBS usage or financial implications.

5.7 The pre-PBAC response claims that if recommended for listing, Lozanoc will not increase the existing itraconazole market. Accordingly, the sponsor expects that the addition of Lozanoc to the PBS, at the same price as current itraconazole, would be cost-neutral to the Government.

*For more detail on PBAC’s view, see section 6 “PBAC outcome”*

## **6 PBAC Outcome**

- 6.1 The PBAC rejected the submission to list itraconazole 50 mg on the PBS for the treatment of systemic mycoses, as data demonstrating comparative efficacy and safety were not provided in the submission. Accordingly, the PBAC could not recommend (under section 101(3) of the Act) that itraconazole be made available as a pharmaceutical benefit.
- 6.2 The PBAC noted that while the TGA found that the 50 mg capsules were therapeutically equivalent to the currently listed 100 mg itraconazole capsules on appeal, a bioequivalence statement was not issued.
- 6.3 The PBAC considered there would be a small risk of prescriber or patient confusion if itraconazole 50 mg were to be listed. That is, there is a risk that a patient may receive twice the dose intended by the prescriber.
- 6.4 While the PBAC considered there may be a small advantage to adding an additional brand of itraconazole to the PBS, it did not consider there was a compelling clinical need for listing.
- 6.5 The PBAC noted that the submission did not provide data demonstrating comparative efficacy and safety relative to the nominated comparator (itraconazole 100 mg). The PBAC recommended the sponsor address these concerns via a resubmission.
- 6.6 The PBAC noted that this submission is eligible for an Independent Review.

**Outcome:**

Rejected

## **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 strongly disagrees with the decision and is considering its position regarding any future course of action. The TGA approved Product Information (PI) states: that one capsule of LOZANOC 50 mg is therapeutically equivalent to one 100 mg capsule of conventional itraconazole capsules; can be taken regardless of food and of gastric acid inhibitors; with less intra- and inter-subject variation in the extent of exposure than conventional itraconazole capsules. Given Lozanoc is the only 50 mg capsule of itraconazole available in Australia, and the Lozanoc PI highlights that Lozanoc and Sporanox are not interchangeable, the risk of prescriber and patient confusion is negligible.