Clarification on the Classification of Azelastine for Nasal Use

Reason for Submission

Medsafe has received a New Medicine Application for a nasal spray that contains 0.15% $^{w}/_{v}$ azelastine hydrochloride, and is indicated for the treatment of hayfever symptoms caused by seasonal and non-seasonal allergies including pollen, house mites and pet hair.

Azelastine is currently classified as:

- Prescription; except when specified elsewhere in the Schedule
- Pharmacy-only; **for nasal use**; in topical eye preparations containing 0.05% or less

The current nasal use classification does not include a strength limit. This is despite the fact that the only azelastine-containing nasal spray (Azep) currently approved in New Zealand is formulated at a lower strength (0.1% $^{w}/_{v}$) of azelastine hydrochloride.

Medsafe requests confirmation from the Medicines Classification Committee (MCC) that the pharmacy-only classification of azelastine hydrochloride remains appropriate when present in nasal preparations at 0.15% $^{w}/_{v}$.

Background

Previous MCC classification recommendations (relevant to nasal use)

At the 16th MCC meeting on 24 April 1996 it was recommended that azelastine be scheduled as a prescription medicine.

At the 17th MCC meeting on 15 May 1997, as a result of a company submission, it was recommended that azelastine be down-scheduled from prescription medicine to pharmacy-only medicine for nasal use[1]. The minutes do not record any discussion regarding strength. However, the only product under consideration at the time was Azep (formerly called Rhinolast), a nasal spray containing 0.1% $^{w}/_{v}$ of azelastine hydrochloride.

Overseas classification of azelastine

Both the 0.1% and 0.15% $^{w}/_{v}$ strengths of azelastine hydrochloride nasal spray are marketed as pharmacy-only medicines in Australia. This includes Astepro (the subject of the New Medicine Application received by Medsafe), which was approved by the TGA in December 2013

In the United Kingdom, azelastine hydrochloride is a prescription medicine when for nasal use, except when:

- it is indicated for the treatment of seasonal or perennial allergic rhinitis in adults and children not less than 5 years
- maximum dose is 140 mcg per nostril

- maximum daily dose is 280 mcg per nostril
- maximum pack is 5040 mcg of azelastine hydrochloride.

Under these conditions, azelastine hydrochloride is pharmacy only.

The 0.15% $^{w}/_{v}$ strength product would be a prescription medicine in the UK as it delivers 205.5 mcg of azelastine HCl per nostril (equivalent to 187.6 mcg of azelastine base). The 0.1% $^{w}/_{v}$ strength would be pharmacy only as each spray contains 140 mcg of azelastine hydrochloride, and may be administered as a maximum of two sprays per day per nostril.

Azelastine hydrochloride nasal sprays in New Zealand

The only currently approved nasal spray preparation in New Zealand contains azelastine hydrochloride at 0.1% $^{w}/_{v}$ strength (Azep, approval date 1997).

The recent New Medicine Application received by Medsafe is for Astepro, a nasal spray solution containing azelastine hydrochloride at 0.15% $^{w}/_{v}$. This application is pending, but sufficient information was provided in the initial application for Medsafe to conclude that no new clinical or safety concerns have been identified at the increased strength. A copy of the full clinical evaluation report[2] is attached for the MCC's convenience.

Conclusion

Based on the information submitted in the New Medicine Application for Astepro, it appears appropriate for a 0.15% $^{w}/_{v}$ azelastine hydrochloride nasal spray to be classified as pharmacy-only.

However, Medsafe requests confirmation of this interpretation as previous discussions of azelastine for nasal use by the MCC were centred on a lower strength product.

Medsafe also recommends that, to avoid any confusion in the future, a strength limit should be included in the pharmacy-only scheduling of azelastine for nasal use. A reasonable limit would be 0.15% $^{w}/_{v}$ azelastine hydrochloride as no products (approved or pending) contain more than this concentration. The classification wording for azelastine should, therefore, be amended to:

- Prescription; except when specified elsewhere in the Schedule
- Pharmacy-only; **for nasal use in preparations containing 0.15% azelastine hydrochloride or less**; in topical eye preparations containing 0.05% or less

Attachments

1. Extract from Minutes of the 17th Medicines Classification Committee, 15 May 1997
2. Clinical evaluation report for Astepro (0.15% $^{w}/_{v}$ azelastine hydrochloride)