Submission for medicine reclassification for consideration by the Medicines Classification Committee

Introduction

Allergic conjunctivitis is a common condition that can be seasonal (e.g. triggered by pollen at certain times of the year) or perennial (year-round). It is usually self-managed with oral treatments and/or eye drops.

Antihistamine eye drops are one of the first-line recommendations to manage allergic conjunctivitis [1].

Bilastine is a second-generation antihistamine already available in New Zealand as a pharmacy only medicine in oral formulations containing 10 mg or 20 mg per tablet for children or adults, respectively.

This application seeks the classification of Bilastine eye drops (6 mg/mL) as a pharmacy-only medicine, in line with its safety and tolerability. These eye drops provide an important addition to patient choice, being effective, comfortable to use, once-daily and preservative-free.

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

Bilastine

2. Proprietary names (if applicable)

Labixten

3. Name and contact details of the company/ organisation/ individual requesting a reclassification

Contact details can be removed from the form prior to publication of the Medsafe website if requested.

A. Menarini New Zealand Pty Ltd. 4 Whetu Place, Rosedale, Auckland 0632. Phone: 0800 102 349.

A. Menarini New Zealand is the sponsor of Labixten.

4. Dose form(s) and strength(s) for which a change is sought (if applicable)

Bilastine 6 mg/mL eye drops.

Note: there is no need to include the strength on the classification statement. Other ocular antihistamines, e.g. lodoxamide do not specify strength in their classification statement in New Zealand.

5. Pack size, storage conditions and other qualifications (if applicable)

The product is currently packaged in a multi-dose 5mL bottle and is stored below 25°C.

However, neither need to be specified on the classification statement - other ocular antihistamines in New Zealand, e.g. lodoxamide do not include pack size in the classification statement.

6. Indications for which change is sought (if applicable)

The licensed indication will be: Treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis.

However, the indication does not need to be specified on the classification statement. For example, other ocular antihistamines in New Zealand, e.g. lodoxamide do not specify indications.

7. Present classification of the medicine

Prescription: except when specified elsewhere in this schedule
Pharmacy only: for oral use.

8. Classification sought

Pharmacy only: for oral use; for ophthalmic use in adults **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

This classification aligns with most other oral antihistamines (for oral use), and also aligns with most other antihistamine eye drops as it allows the optometrist to supply them as well as being pharmacy only. See point 11 below.

For example, Levocabastine is a pharmacy only medicine: for nasal use; for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

9. Classification status in other countries (especially Australia, UK, USA and Canada), and any justification for harmonisation

Bilastine for oral preparations is available without Doctor's prescription for adult and paediatric use in various countries which include:

Australia, Austria, Czech Republic, Germany, Poland, Lithuania, Latvia, Switzerland, Russia, Moldavia, Georgia, Singapore, South Africa, Turkmenistan, Thailand and Malaysia, Spain and Portugal.

In detail, for Australia, the classification status is currently the following:

- Schedule 2 (pharmacy-only): Bilastine in oral preparations up to a daily dose of 20 mg for the treatment of adults and children aged 12 years and over.
- Schedule 3 (pharmacist-only): Bilastine in oral preparations up to a daily dose of 10 mg for children aged 6-11 years.

Bilastine for oral preparation for adult use is registered as a prescription medicine in Canada and the United Kingdom, while it is not registered in the United States of America.

[redacted]

Bilastine remains prescription medicine in Canada, however, pharmacists in many provinces have prescribing rights for continuation supply, for minor conditions and/or for allergic rhinitis [2], so a reclassification would not necessarily be needed for supply without a prescription.

While, with regards to Bilastine eye drops, it was classified as pharmacy only in Austria on 9th of March 2023 [redacted]

Please note that Bilastine eye drops has lower systemic bioavailability than tablets that are accepted as non-prescription.

Bilastine eyedrops is not registered in United Kingdom, Canada, Australia, United States or Japan.

[redacted]

10. Extent of usage in New Zealand and elsewhere (e.g. sales volume) and dates of the original consent to distribute

Although Bilastine tablets have been available in New Zealand since 2018, the eye drops have not yet been registered in New Zealand.

Bilastine eye drops have been registered in Europe through the Decentralised Procedure with the procedure completed 29 June 2022 for 22 EU countries. The first marketing authorisation was issued in Ireland on 22 July 2022, which is the international birth date. Bilastine eye drops have also been registered in Switzerland. To date, Bilastine eye drops have not been registered in Australia, the UK, the US or Canada.

[redacted]

While Bilastine eye drops have relatively low uptake so far, the experience with the oral formulation is substantial. By March 2024, Bilastine 20 mg tablets form had been registered in 39 European countries (26 EU-Member States and 13 Non-EU Member States) and 87 other countries, and [redacted] Bilastine 20 mg orodispersible tablets was authorised in February 2023, in France. To date, the product is registered in a total of 25 countries in Europe (24 EU-Member States and 1 Non-EU Member States) and in one country outside Europe. [redacted]

Bilastine 10 mg orodispersible tablets was first authorised in July 2017 in the United Kingdom. [redacted]

11. Local data or special considerations relating to New Zealand (if applicable)

Bilastine eye drops are not yet marketed or registered in New Zealand.

There is a long-standing history of non-prescription (pharmacy-only) availability of eye drops medicines for allergy. This includes lodoxamide (a mast cell stabiliser, classified as pharmacy only since before 2000[3]), levocarbastine (antihistamine), azelastine (antihistamine), ketotifen (antihistamine and mast cell stabiliser), sodium cromoglycate (mast cell stabiliser), pheniramine (antihistamine combined with the decongestant naphazoline) and antazoline (antihistamine). The longstanding non-prescription availability of these treatments reinforces that allergic eye conditions can be effectively self-managed in a pharmacy environment. Additionally these medicines have a well-established safety profile.

From 2008, many eye drops were able to be supplied also by optometrists.

The following classification statements apply to products with the same use:

- Lodoxamide: pharmacy only for ophthalmic use **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- Azelastine: pharmacy only in preparations for nasal use containing 0.15% azelastine hydrochloride or less; in topical eye preparations containing 0.05% or less
- Levocabastine: pharmacy only for nasal use; for ophthalmic use **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

- Antazoline: pharmacy only for ophthalmic use **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board
- Ketotifen: pharmacy only for ophthalmic use in medicines containing 0.02% or less **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

- Sodium cromoglycate: pharmacy only for nasal use; for ophthalmic use **except** when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board.

In addition to eye drops, other treatments for allergy have been available for many years without a prescription, including oral antihistamines, nasal antihistamines, nasal mast cell stabilisers and nasal corticosteroids.

12. Labelling or draft labelling for the proposed new presentation(s) (if applicable)

Please see attached draft labelling.

13. Proposed warning statements (if applicable)

It is proposed that the draft labelling includes the following:
Do not use Labixten eye drops:
- If you are allergic to Bilastine or any other ingredients in this medicine
- If you are under 18 years of age

Consult a pharmacist or doctor:
- For use of more than 8 weeks
- If symptoms persist or appear to worsen
- If you experience any side effects that concern you

14. Other products containing the same active ingredient(s) which would be affected by the proposed change

None

Part B– Clinical Context and Implications

Bilastine is a non-sedating antihistamine already available in NZ as a pharmacy medicine in oral form for adults and children and used for allergic rhinitis. The eye drops formulation have the convenience of one drop in the affected eye once-daily , quick action and comfort in instillation[4], which will provide considerable benefit to users. Bilastine eye drops are formulated with hyaluronic acid and free of preservatives and phosphates. Bilastine eye drops are compatible with contact lenses.

Bilastine is a non-sedating, long-acting second-generation histamine antagonist with selective peripheral H1 receptor affinity and no apparent affinity for muscarinic receptors. Bilastine antagonises histamine, stabilises mast cells and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells and thus prevents itching, vasodilation and vascular leak leading to ocular redness, chemosis and blepharitis. Chemosis is swelling of the tissue lining the eyelids and conjunctiva from fluid build-up.

15. Indications and dose

- *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*
- *What is the evidence that the proposed indication is an OTC indication ie, that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?*

- *What is the treatment population for the indication (age, gender etc.)?*
- *What is the dose and dose frequency of the medicine for this indication?*

The proposed indication for Labixten eye drops upon registration will be: Treatment of ocular signs and symptoms of seasonal and perennial allergic conjunctivitis.

The proposed outer packaging upon registration will include the following wording: Relief of hayfever and allergy symptoms: red/itchy/watery eyes.

Note that, in line with classification statements for similar medicines, the indication does not need to be stated in the classification statement.

The justification for the proposed indication for the OTC classification is supported by the long history of self-management of allergic rhinitis. Oral and ocular treatments for allergic rhinoconjunctivitis or allergic conjunctivitis have been available without prescription in New Zealand for decades.

Allergic conjunctivitis is easy to recognize, as it presents symptoms such as red, itchy and/or watery eyes. Most people who experience allergic conjunctivitis do so regularly when exposed to antigens, e.g. pollen, dust, cat dander. They quickly learn how to manage it and can easily seek advice from the pharmacy staff if needed. Additionally, pharmacy staff are well trained in managing allergic rhinitis, ensuring appropriate guidance is available when required.

In case a person takes Bilastine eyedrops and does not have relief from symptoms because it is not an allergy, the symptoms will not be masked by the product and the patient can check with a pharmacist or can see a doctor. For this reason, the proposed label would state to "consult a pharmacist or doctor if symptoms persist or appear to worsen."

The recommended dose is one drop once a day as required in the affected eye/s; the solution contains Bilastine 6 mg/mL and each drop contains 0.2 mg of Bilastine. Since both eyes will be usually affected, the total daily ocular dose would be 0.4 mg. This dose is straightforward, very easy to manage.

The treatment population is adults. There is no maximum age.

16. Presentation

- *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*
- *What disposal considerations need to be made for the medicine?*
- *How practical and easy to use is the proposed presentation?*

The proposed dose form is ocular solution (eye drops) containing Bilastine 6 mg/mL.

The disposal considerations follow standard practice for eye drops. However, please note that the preservative-free multi-dose container will generate less waste than

preservative-free single-dose containers, so it has environmental benefits. Additionally, the 8 weeks shelf-life under usage conditions will reduce waste compared to products involving a single pack per month.

The recommended dose is one drop once a day as required in the affected eye/s, which makes the once-daily dosage convenient to use. The eye drop bottle is easy to use.

17. Consumer benefits

- *What is the history of this medicine's use for the proposed indication(s) ie, number of users; number of countries used in?*
- *To what extent is this medicine used for the proposed indication(s) ie, duration of use; frequency of use?*
- *What is the evidence that improved access is beneficial for the individual?*
- *What is the evidence of improved consumer involvement in their health?*
- *What are the benefits from a consumer viewpoint?*

Bilastine has been used in many countries since first being registered in Iceland on 23 September 2010 in its oral formulation. As of March 2024, Bilastine 20 mg tablets was registered in 39 European countries, and 87 other countries including the United Kingdom, Canada, New Zealand, Singapore, Switzerland, Australia and Japan. [redacted]

The ocular formulation is more recent, being first registered in Ireland on 22 July 2022. As of March 2024, Bilastine eye drops was registered in 23 countries, 22 in the European Economic Area, and in Switzerland. [redacted]

Ocular antihistamines directly target ocular tissues and have a faster onset of action, good tolerance, and a better safety profile than oral antihistamines due to a lower systemic availability [1]. First-line options for allergic conjunctivitis are topical antihistamines, mast cell stabilisers, and dual-acting agents [1].

Bilastine is a non-sedating, long-acting second-generation histamine antagonist with selective peripheral H1 receptor affinity and no apparent affinity for muscarinic receptors. Bilastine antagonises histamine, stabilises mast cells and prevents histamine induced inflammatory cytokine production by human conjunctival epithelial cells, and thus prevents itching, vasodilation and vascular leak leading to ocular redness, chemosis and blepharitis.

Bilastine has been proven more effective than its vehicle and of similar effectiveness to Ketotifen [4]. In the Ketotifen comparison trial, Bilastine was significantly more comfortable at the time of insertion than Ketotifen [4] with duration of at least 16 hours. More people chose the words “smooth” or “soothing” to describe the insertion of Bilastine than for Ketotifen [4].

The treatment of allergic conjunctivitis with eye drops should avoid inducing side effects that disturb tear film homeostasis or trigger excessive inflammation [6].
Research in dry eye disease has found that long-term use of eye drops containing preservatives can destabilize the precorneal tear film and produce adverse effects in the conjunctiva, including conjunctival cell apoptosis, allergic conjunctivitis, and keratitis. In allergic conjunctivitis the ocular surface is already altered, making this effect of preservatives more likely. Therefore, some suggest avoiding preservatives in antihistamine eye drops if possible, as some preservatives can be associated with toxicity or allergy [1, 5]. Prolonged use of benzalkonium chloride, for example, can lead to dry-eye disease [1]. Herrero-Vanrell, et al [5], recently reviewed excipients in antihistamine eye drops, noting that preservative-free eye drops *"significantly improve tolerance and patient comfort while preventing precorneal film denaturation and potentially irreversible damage to the ocular surface".* Multiple guidelines now also recommend avoiding use of preservatives in allergic conjunctivitis [1]. Preservatives can be avoided through single use containers or a multidose eye drop system designed with a one-way valve and a silicon plug which prevents content back contamination (as used with Bilastine eye drops) which allow maintenance of sterility without preservatives [5].

This once-daily multidose preservative-free eye drop formulation of bilastine 0.6% (w/v) contains hyaluronic acid, which helps to preserve the tear film and ocular surface integrity [1].

Bilastine eye drops provide convenience to patients with once daily dosing, able to be used for 8 weeks, and having no preservative. People with allergies will benefit from additional choice, including being able to choose a preservative-free product that is comfortable on insertion and works well for them.

The Sponsor notes that it is uncommon to have in-use shelf-life of 8 weeks on a single container without preservatives. However, this is supported by the stability information which has been accepted in the registration process in other jurisdictions (e.g. EU countries). This will be justified during the registration process where stability is always considered, so it does not need to be further discussed as part of the reclassification application.

18. Contraindications and precautions

- *What are the contraindications for the medicine and how easy are they to identify and prevent?*
- *What are the precautions for this medicine and how easy are these to understand?*
- *Does the medicine have a low therapeutic index?*
- *What class effects need to be considered and what are the risks?*
- *What are the risks of the medicine being used in an OTC environment?*
- *What other drug interactions need to be considered?*
- *What food and/ or drink interactions need to be considered?*
- *Are there any other restrictions when taking the medicine ie, driving restrictions or operating machinery?*
- *Are there any special populations where exposure to the medicine needs to be restricted?*

The only **contraindication** is hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions from the European Summary of Product Characteristics (EU SmPC) is as follows:
Bilastine is an antiallergic/antihistaminic active substance and, although administered topically, it is absorbed systemically. If signs of serious reactions or hypersensitivity occur, treatment should be discontinued.
After dropping Bilastine antiallergic eye drops into the conjunctival sac of the eye, the visual acuity can deteriorate for a few minutes due to the formation of streaks.
Reactions at administration site:
If adverse events at the administration site, such as eye irritation, pain, redness or change in vision occur or if the patient´s condition is worsened, discontinuation of the treatment should be considered.

[redacted]

These contraindications, warnings and precautions are consistent with those expected for antihistamine eye drops and can be easily identified by the patient, who can discontinue use if necessary. A temporary effect on visual acuity is common with eye drops, and users are generally familiar with managing this.
Bilastine has a wide margin of safety.

As a second generation antihistamine it is very well characterised and regarded as very safe. There are no concerning class effects relevant to Bilastine eye drops.

The risks associated with use in an OTC environment are minimal. Bilastine eyedrops will not mask serious conditions, and people are used to self-treating allergies, including with antihistamine eye drops.

Regarding drug interactions the following is stated in the EU SmPC:
"No interaction studies have been performed. Considering the low systemic exposure to Bilastine after ocular administration no clinically relevant interaction with other medicinal products is expected. In case of concomitant therapy with other topical ocular medicines, an interval of 5 minutes should be allowed between successive applications. Eye ointments should be administered last." This is manageable with an OTC medicine.

There are no food or drink interactions to be considered.

For driving the following is stated in the EU SmPC:
"Temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs after instillation, the patient should be advised to wait until the vision clears before driving or using machinery." This is common sense information with eye drops which will may sometimes cause a brief blurring after administration, and in this case people will wait until resolution before they drive or use machines.

Special populations – Bilastine has low systemic absorption and can be used in pregnancy and breast-feeding. No dose adjustments are needed in elderly, patients with renal impairment and hepatic impairment.

Recent data has demonstrated the safe use of Bilastine eye drops also in children (aged 2 and above), however the OTC classification for Bilastine eyedrops is being requested for the adults age group. The proposed packaging states the use of Bilastine eye drops above 18 years of age. Note that the children can use the already available Bilastine in oral form.

19. Undesirable effects

- *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*
- *What are the risks and consequences of known undesirable effects?*
- *Are there any significant safety concerns for the medicine under review?*
- *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*
- *Are there any withdrawal effects following cessation of use of the medicine?*

Bilastine is rapidly absorbed into the blood stream after ocular application. At steady state, Bilastine reached maximum blood levels of 2.7 ng/mL within 2.52 hours after administration, i.e., about 1.5% of Cmax at steady state for Bilastine 20 mg tablets. Thus, systemic adverse effects will logically be uncommon.

The data sheet reports that in a phase III study of 218 patients, only 6 patients on Bilastine eye drops and 5 patients on placebo experienced adverse events.

Adverse effect information from clinical trials is reported in the EU SmPC with the following adverse effects all been reported as "uncommon" (≥ 1/1,000 to < 1/100):
Nervous system disorders:
- Dysgeusia
- Headache

Eye disorders:
- Dry eye
- Eye discharge
- Eye irritation
- Lacrimation increased
- Ocular discomfort

During post-marketing experience with oral Bilastine formulations hypersensitivity reactions have been observed with frequency not known.

The adverse event profile of Bilastine eye drops is very reasonable for a pharmacy-only medicine. Any adverse events that may occur would be easily identifiable by the patient, who can discontinue use if necessary. Hypersensitivity reactions can occur with any medicine and would be managed in the same way as if they occurred with another pharmacy-only medicine.

There are no significant safety concerns associated with bilastine eye drops. Antihistamine eye drops have a long history of use worldwide. Maximum blood levels are only about 1.5% of the Cmax of one Bilastine 20 mg tablet.

There have been no withdrawals or regulatory actions taken with Bilastine. There will be no withdrawal effects with this medicine.

20. Overdose

- *Is there a potential for overdose of the medicine?*
- *What are the consequences of overdose of the medicine?*
- *Are there any reports of overdose of the medicine?*

The potential for overdose is minimal given the low level of absorption (one drop in each eye provides blood levels about 1.5% of a 20 mg tablet).
The EU SmPC notes:
No specific reactions after ocular overdose are known and with ocular use, overdose reactions are not anticipated as excessive fluid will flow out of the eye quickly.
In phase I clinical trials with oral formulations, doses up to 11 times (single dose) and up to 10 times (multiple dose), the human recommended oral dose have been tested, without any safety problems.

In the unlikely event that a child inadvertently swallowed the contents of the bottle this would be 30 mg (5 mL containing 6 mg/mL), equivalent to 1.5 Bilastine tablets which would be very low risk.

21. Medication errors and abuse/ misuse potential

- *Would reclassification affect the risk of unnecessary use?*
- *Should the medicine be provided with necessary tools to allow correct dosing eg, liquids supplied with a measuring device?*
- *What are the reported medication errors post-market?*
- *What are the reported cases of abuse/misuse/accidental overdose?*
- *How would reclassification affect import considerations?*
- *What is the addiction potential of the medicine?*

Reclassification will not affect the risk of unnecessary use – people will only use these eye drops when experiencing ocular symptoms. The product will be clearly labelled, providing guidance for appropriate use, and there would be no rationale for unnecessary use.

The dropper will allow one drop to be gently squeezed from the bottle, one drop is a single dose.

Bilastine eye drops solution has been registered in Europe by the Company through Decentralised Procedures (DE/H/2300/005/DC, DE/H/2301/005/DC and DE/H/2302/005/DC), positively ended on 29-Jun-2022, for the treatment of ocular

symptoms at the current dose of one drop in the affected eye(s) once daily (corresponding to 0.2 mg of bilastine). [redacted]

Please note that the oral tablets of Bilastine were first registered in Europe in 2010, and have a high usage rate than the eye drops, and have been accepted as appropriate for pharmacy-only classification. Bilastine eye drops would have minimal risk given the low systemic absorption and features of the medicine, as antihistamine eye drops for allergy.

Reclassification will affect import considerations in the same way as other eye preparations for allergy that are pharmacy-only, there is no additional risk compared to other medicines in this category.

There is no addiction potential of this medicine.

22. Communal harm and/or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)?*
- *What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?*

There are no possibilities of community harm resulting from non-prescription use of Bilastine eye drops.

There is no community benefit from wider use of Bilastine eye drops.

23. Integrated benefit-risk statement

- *A summary of the reclassification benefits*
- *A summary of the reclassification risk of harm*
- *A summary of the need for the medicine at the classification proposed*
- *Precedent – how are other medicines in the same class classified?*

Benefits: Bilastine eye drops is an effective medicine with low systemic absorption and fast action, it provides comfort in usage and contains no preservatives. It is used once daily which is convenient for patients.

Availability of an effective ocular formulation of antihistamine should reduce use of topical decongestants which can cause rebound congestion in long-term use and do not address the cause of the condition [1].

Risks:

- Minimal – possible use without wiping the nozzle as recommended - this is advised on the packaging
- Potential temporary drop in visual acuity following the instillation of the eye drops affecting driving ability – this will be expected by patients (as it can occur with other eye drops), would be easily identified and brief, and it is unlikely that the patient will drive immediately after instillation if their vision is blurry. Additionally, the once-a-day usage reduces the likelihood of using the eyedrops just before driving.
- Hypersensitivity reaction – this can occur with any OTC medicine and will be handled in the same way as with other medicines.

This medicine as a pharmacy-only medicine follows other similar products and will provide a useful choice for patients.

24. Risk mitigating strategies

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc?*
- *What is the evidence that these proposed risk mitigation strategies would be effective?*
- *What post-market surveillance activities would be carried out?*
- *Is the proposed reclassification supported by professional bodies?*

The packaging will provide all the information needed to be known by people using this medicine. Furthermore, people are used to self-managing allergy symptoms.
This risk mitigation strategy - of packaging and relying on people to self-manage allergy symptoms - has been accepted without concern for other eye drops for treatment of allergy and there is no reason not to accept it for Bilastine eyedrops.

As a pharmacy-only medicine, Bilastine eyedrops will be supplied by pharmacy staff, supervised by a pharmacist. A pharmacist will always be available to discuss the condition. Pharmacy assistants and pharmacists will often ask someone with an allergy when they request a product by name "how well is that working for you?" This allows a discussion about best management options for an individual.

No additional post-market surveillance activities would be carried out except for the collection of spontaneous adverse reaction data by the sponsor company, as standard practice.

We will leave the professional bodies to submit themselves rather than speaking on their behalf.

Conclusion

A brief summary of the purpose of the submission and any concluding remarks

This application seeks to classify a second-generation antihistamine eye drop product as a pharmacy-only medicine. The active ingredient, Bilastine, is already available in New Zealand as a pharmacy-only medicine in oral form for both adults and children, with greater systemic exposure to the ingredient. Having the well-tolerated and effective Bilastine eye drops as a once-daily formulation without preservatives but in a multi-dose container is consistent with other decisions to have antihistamine eye drops able to be used for allergy self-management and provides choice to patients.

References

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