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ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DURATEARS Z, eye ointment.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DURATEARS Z eye ointment does not contain any active substance.
For a complete list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
White to light yellow, transparent, homogeneous ointment

4. CLINICAL DATA

4.1 Therapeutic indications

- For protection and as an adjuvant in case of corneal exposure due to traumatic eyelid damage and peripheral facial nerve palsy;
- corneal dehydration with reduced tear production;
- recurrent corneal erosions, where the use of DURATEARS Z eye ointment overnight prevents eyelid adhesion;
- preoperatively as a protective agent for the cornea during procedures under general anaesthesia.

4.2 Dosage and method of administration

Apply a small amount of ointment (approx. 0.5 cm) to the lower eyelid as often as necessary or as prescribed by the ophthalmologist.

Elderly patients
A dose adjustment in the elderly is not necessary.

Paediatric patients
The safety and efficacy of DURATEARS Z eye ointment in children has not been established. However, dose adjustment is not expected before use.

Patients with liver or kidney dysfunction
The safety and efficacy of DURATEARS Z eye ointment in patients with liver/kidney dysfunction has not been established. However, dose adjustment is not expected to be necessary for use in these patients.

Method of administering
- For ocular use.
- Remove contact lenses before use.
- The ointment should be applied under hygienic conditions, avoid any contact with the tip of the tube. Close the tube after each use.
- If a patient is taking more than one topical ocular medicinal product, an interval of at least 5 minutes between consecutive administrations should be respected. Eye ointments should be applied last.

4.3 Contraindications

Hypersensitivity to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For ophthalmic use only. Not intended for injection or oral ingestion.

If patients experience headache, eye pain, vision changes, eye irritation or persistent redness, or if their condition worsens or persists, they should discontinue using the medicinal product and consult their medical professional.

Contact lenses should not be worn during treatment with DURATEARS Z eye ointment. Remove contact lenses prior to using DURATEARS Z eye ointment.

DURATEARS Z eye ointment contains wool fat, which may cause localised skin reactions (such as contact dermatitis).

4.5 Interactions with other medicinal products and other types of interaction

No interaction studies have been conducted.

If a patient is taking more than one topical ophthalmic medicine, there should be at least 5 minutes between each administration. Eye ointments should be administered last.

4.6 Fertility, pregnancy and lactation

Fertility
There are no data to suggest that wool grease, liquid paraffin or white, soft paraffin have a negative impact on male or female fertility. All of these components of Duratears Z are pharmacologically inert. For this reason, no effects on fertility are expected.

Pregnancy
There are no or limited data on the use of DURATEARS Z eye ointment in pregnant women. The ingredients white petroleum jelly, liquid paraffin and lanolin (wool fat) are pharmacologically inert. As a result of negligible systemic exposure after ocular administration, no effects during pregnancy are expected. DURATEARS Z eye ointment can be used during pregnancy.

Breastfeeding
It is unknown whether white vaseline, liquid paraffin, or lanolin (wool fat) are excreted in human breast milk. However, no effects on breast-fed newborns/infants are expected as the breast-feeding woman's systemic exposure to this medicinal product is negligible after ocular administration and because all of the components of Duratears Z are pharmacologically inert agents. For this reason, no adverse effects are expected during breastfeeding. DURATEARS Z eye ointment can be used during breastfeeding.

4.7 Effect on the ability to drive and operate machinery

DURATEARS Z eye ointment has no or negligible influence on the ability to drive and operate machinery. As with any eye ointment, temporary blurred vision or other visual disturbances may affect the ability to drive and use machines after administration of the eye ointment. If blurred vision occurs during administration, the patient should wait until the vision is clear again before driving vehicles or using machines.

4.8 Side effects

The following side effects have been reported after the administration of DURATEARS Z eye ointment. Its frequency cannot be determined from the available data.

System/organ class	MedDRA Preferred Term (v. 14.1)
Eye disorders	Eye pain, swelling of the eye, itchy eyes, feeling of a foreign body in the eye, blurred vision, eye discomfort, eye irritation, conjunctival oedema, abnormalities in the cornea, increased teardrop production.
Nervous system disorders	Headache

Reporting of suspected side effects
It is important to report suspected side effects after authorisation of the medicine. In this way, the relationship between benefits and risks of the medicine can be continuously monitored. Healthcare professionals are asked to report any suspected side effects via the national reporting system:
Netherlands Side Effects Centre Lareb
Website: www.lareb.nl

4.9 Overdose

Due to the properties of this preparation, no toxic effects are expected in the event of topical ophthalmic overdose of this medicinal product or accidental ingestion of the contents of one tube. An overdose of DURATEARS Z eye ointment can be washed out of the eye with lukewarm water.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: artificial tears and other indifferent preparations, ATC code: S01XA20

DURATEARS Z eye ointment does not contain any active substance. The ointment base melts easily in the eye and prevents corneal dryness.

DURATEARS Z eye ointment is a sterile mixture of white paraffin, anhydrous liquid lanolin and mineral oil and contains no pharmacologically active ingredient; it has a physical action as an ocular lubricant.

Pharmacodynamic studies with DURATEARS Z eye ointment have not been performed; therefore, no pharmacodynamic data are available.

5.2 Pharmacokinetic properties

White soft paraffin/liquid paraffin/wool grease (also known as lanolin) have no pharmacological activity. As a result, no components of the pharmacokinetic data are available.

5.3 Preclinical safety data

Non-clinical data do not indicate a special risk for humans. These data come from conventional studies in safety pharmacology, repeat-dose toxicity, genotoxicity, carcinogenic potential, and reproductive and developmental toxicity.

6. PHARMACEUTICAL DATA

6.1 List of excipients

White vaseline,
liquid wool fat (lanolin),
liquid paraffin.

6.2 Cases of incompatibility

Not applicable.

6.3 Shelf life

3 years
Discard 4 weeks after first opening.

6.4 Special precautions for storage

Store below 25°C. Do not store in the refrigerator or freezer.

6.5 Nature and contents of packaging

3.5 g sterile eye ointment in an aluminium tube with epoxy-phenol coating and polyethylene nozzle and screw cap.

6.6 Special precautions for disposal

No particular requirements. All of the unused medicinal product or waste material must be destroyed in accordance with local regulations.

7. MARKETING AUTHORISATION HOLDER

Alcon Nederland B.V.
Avelingen-West 64
4202 MV Gorinchem

8. MARKETING AUTHORISATION NUMBER

DURATEARS Z eye ointment is registered under RVG 10380.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 4 June 1984
Date of last renewal: 4 June 2014

10. DATE OF REVISION OF THE TEXT

Last partial revision concerns heading 7: 5 April 2019