## 1. NAME OF THE MEDICINAL PRODUCT

DURATEARS.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This medicine contains no active substance.
Excipient with known effect: 1g eye ointment contains 30 mg lanoline
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Eye ointment
White to light yellow, translucent, homogeneous ointment

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Eye dryness

### 4.2 Posology and method of administration

Posology
At night, before going to bed, apply a small amount of ointment into the conjunctival sac or to the affected spot.
*Pediatric population*
The safety and efficacy of DURATEARS eye ointment in children has not been established.
Hepatic and Renal Disease
The safety and efficacy of DURATEARS eye ointment in subjects with hepatic/renal disease has not been established; however, no dosage modifications are expected to be required for use in this population.
Method of administration x For ocular use.

- x Remove contact lenses before using.
- x Application of the ointment should be carried out under hygienic conditions, avoiding any contact to the tip of the tube. Close tube after every application.
- x If a patient is receiving more than one topical ophthalmic drug, the drugs should be administered at least 5 minutes apart. Eye ointments should be administered last (see section 4.5).

### 4.3 Contraindications

Hypersensitivity to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

For ocular use only. Not for injection or ingestion.
If patients experience headache, eye pain, vision changes, irritation of the eyes, persistent redness, or if the condition worsens or persists for more than 3 days, they are to discontinue use and consult their doctor.
Contact lenses may not be worn during treatment with DURATEARS eye ointment. Remove contact lenses before using DURATEARS eye ointment.
DURATEARS eye ointment contains lanoline, which may cause local skin reactions (e.g. contact dermatitis).

### 4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.
No clinically relevant interactions have been described.

If a patient is receiving more than one topical ophthalmic drug, the drugs should be administered at least 5 minutes apart. Eye ointments should be administered last (see section 4.2).

**4.6 Fertility, pregnancy, and lactation**

Pregnancy
There are no or limited amount of data from the use of DURATEARS eye ointment in pregnant women. All of the components are pharmacologically inert compounds or generally classified as non-toxic and nonirritating (See Section 5.3). Therefore, no adverse effects during pregnancy are anticipated. DURATEARS eye ointment can be used during pregnancy.
Breast-feeding
It is unknown whether white soft paraffin, liquid paraffin or lanolin (wool fat) are excreted in human milk. However, no effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to the product is expected to be negligible. All of the components are pharmacologically inert compounds or generally classified as non-toxic and non-irritating (See Section 5.3). Therefore, no adverse effects during breastfeeding are anticipated. DURATEARS eye ointment can be used during breast-feeding.
Fertility
There is no adequate data regarding the impact of DURATEARS eye ointment on male or female fertility. All of the components are pharmacologically inert compounds or generally classified as non-toxic and nonirritating (See Section 5.3). Therefore, no effects on fertility are anticipated.

**4.7 Effects on ability to drive and use machines**

DURATEARS eye ointment has no or negligible influence on the ability to drive or use machines. As with any other eye preparation, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines after application of the ointment. If blurred vision occurs at application, the patient must wait until the vision clears before driving or using machinery.

**4.8 Undesirable effects**

Tabulated list of adverse reactions
The following adverse reactions have been reported following administration of DURATEARS eye ointment. Frequencies cannot be estimated from the available data (not known).

| **System Organ Classification** | **MedDRA Preferred Term (v. 14.1)** |
|---|---|
| Nervous system disorders | *Not known:* Headache |
| Eye disorders | *Not known:* Eye pain, eye swelling, eye pruritus, ocular discomfort, eye irritation, eye oedema, foreign body sensation in eyes, ocular hyperaemia, lacrimation increased, vision blurred. |

Description of selected adverse reactions
DURATEARS eye ointment contains Lanolin (Wool Fat) which may cause local skin reactions (e.g. Contact dermatitis).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

**4.9 Overdose**

Symptoms
No case of overdose has been reported.
Due to the characteristics of this preparation, no toxic effects are to be expected with a topical ophthalmic overdose of this product, nor in the event of accidental ingestion of the contents of one tube.
Management
A topical overdose of DURATEARS eye ointment may be flushed from the eye(s) with lukewarm water.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: artificial tears and other indifferent preparations, ATC code: S01X A 20
DURATEARS eye ointment is a sterile mixture of white soft paraffin, anhydrous liquid lanolin and liquid paraffin and has no pharmacological active ingredient; it has a physical action as an ocular lubricant. It leaves a smooth, softening and durable film protecting the eye at night.
Pharmacodynamic studies with DURATEARS eye ointment have not been performed; therefore, no pharmacodynamics data are available.

### 5.2 Pharmacokinetic properties

White soft paraffin/liquid paraffin/wool fat (also known as Lanolin) eye ointment are ophthalmic emollients and neither of them have pharmacological activity. Therefore, no components of the pharmacokinetic data is available. Following oral feeding of wool-fat to cats indicate wool fat is not absorbed from the intestine.

### 5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies or risk assessments of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Anhydrous liquid lanolin
Liquid paraffin
White soft paraffin

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

The expiry date of the product is indicated on the packaging material.

Discard 4 weeks after first opening.

### 6.4 Special precautions for storage

Store at room temperature (15-25°C).

### 6.5 Nature and contents of container

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

### 6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Lapidot Medical, Import and Marketing Ltd.
Hashita St. 8
Industrial Park, Caesarea 38900

## 8. REGISTRATION **NUMBER**

109-33-24050-00
Approved in : 10/2022