SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DEPORES FREE 0.05% Eye Drops, Emulsion
Sterile, preservative-free.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:
Active substance:
Ciclosporin 0.5 mg
Excipient(s):
Castor oil 12.5 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, emulsion.
Preservative-free, white, homogeneous opaque emulsion with no phase separation.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory medicines or using punctal plugs.

4.2 Posology and method of administration

Posology/frequency and duration of administration
The recommended dosage is 1 drop of DEPORES FREE into each eye 2 times a day, approximately 12 hours apart.

Method of administration
DEPORES FREE is applied by instillation into the eye. To prevent eye injury and contamination of the dropper tip and solution, care should be taken to ensure that the dropper tip of the bottle does not touch the eye, eyelids, surrounding area or other surfaces. The bottle should be kept tightly closed when not in use. DEPORES FREE can be used in combination with artificial tears. There should be a 15-minute interval between instillations of the preparations.

Additional information on special populations
Renal / Hepatic impairment
There are no reports regarding topical ophthalmic use in this population.

Pediatric population
The efficacy and safety of DEPORES FREE in children under 16 years old have not been established.

Geriatric population
The efficacy and safety of DEPORES FREE do not differ between younger and older patients.

4.3 Contraindications

DEPORES FREE is contraindicated in patients with active ocular infection and in patients with known or suspected hypersensitivity to any of its ingredients.

4.4 Special warnings and precautions for use

DEPORES FREE is intended for ophthalmic use only.

To avoid eye injury and contamination of the emulsion, the dropper tip should not be contacted with the eye or any surface.

DEPORES FREE eye drops, emulsion has not been studied in patients with a history of herpes keratitis.

DEPORES FREE should not be instilled into the eyes while wearing contact lenses. Typically, patients with reduced tear production should not use contact lenses. If contact lenses are present in the eye, they should be removed prior to instillation of the emulsion. Lenses can be reinserted 15 minutes after DEPORES FREE is instilled.

The efficacy and safety of DEPORES FREE in children under 16 years old have not been established.
The efficacy and safety of DEPORES FREE do not differ between younger and older patients.

No increase in ocular bacterial or fungal infections has been reported following the administration of DEPORES FREE.

DEPORES FREE contains castor oil, which may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

DEPORES FREE can be used in combination with artificial tears. There should be a 15-minute interval between instillations of the preparations. Topically administered DEPORES FREE is not expected to interact with systemic medicines. There is not much information available on the interaction of topical ophthalmic ciclosporin with co-administered ophthalmic medicines.

4.6 Pregnancy and lactation

General advice
Pregnancy category is C.

Women of childbearing potential/Birth control (Contraception)
There are no data available for women of childbearing potential.

Pregnancy
Animal studies are insufficient in terms of effects on pregnancy and/or embryonal/fetal development and/or birth and/or postnatal development. The potential risk for humans is unknown.
DEPORES FREE should not be used in pregnant women unless clearly necessary. If it is necessary, it should be used under the supervision of a doctor after assessing the risk/benefit ratio on the fetus.

Lactation
It is not known whether the medicine passes into breast milk. Therefore, if it is necessary, it should

be used under the supervision of a doctor after assessing the risk/benefit ratio.

Fertility
No effect on human reproductive ability/fertility has been reported for topical ophthalmic use.

4.7 Effects on ability to drive and use machines
As with all ocular medicines, if temporary blurring of vision occurs following drug administration, patients should wait until their vision becomes clear again before driving or operating machines.

4.8 Undesirable effects
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Eye disorders
Very common : Burning in the eye
Common : Conjunctival hyperemia; ocular discharge; epiphora (tearing); pain, foreign body sensation, itching and stinging in the eye; visual impairment (mostly blurred vision)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

4.9 Overdose
No overdose has been reported in humans with ophthalmic use of DEPORES FREE. In cases of suspected overdose, general symptomatic and supportive treatment can be implemented.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Ophthalmologicals, other ophthalmologicals
ATC Code: S01XA18

DEPORES FREE (ciclosporin ophthalmic emulsion) contains ciclosporin, a topical immunomodulator with anti-inflammatory effects.

Ciclosporin is an immunosuppressive agent when administered systemically. Ciclosporin emulsion is thought to act as a partial immunomodulator in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. The exact mechanism of action is not known.

5.2 Pharmacokinetic properties
General properties
Ciclosporin A concentrations in the blood after cyclosporine administration to the eye were measured by specific high-pressure liquid chromatography-mass spectrometry assay. In humans, after topical application of ciclosporin twice daily for 12 months, blood concentrations of ciclosporin were found to be below the detection limit of 0.1 ng/mL. No drug accumulation in the blood was detected during 12 months of treatment with ciclosporin ophthalmic emulsion.

Data on absorption, distribution, biotransformation and elimination regarding ocular administration

have not been reported.

5.3 Preclinical safety data
Preclinical effects have been observed upon systemic administration, which are considered to exceed sufficiently the maximum administration in humans, and are of little clinical significance. No treatment-related systemic or ocular toxicity has occurred. In multiple dosing, no system in which the medicine accumulates has been identified.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Castor oil
Polysorbate 80
Carbomer
Glycerol
Sodium hydroxide
Water for injection

6.2 Incompatibilities
There are no known incompatibilities.

6.3 Shelf life
24 months.
If the bottle is opened once, the product should be used within 90 days. During this period, the product can be stored at room temperature below 25°C.

6.4 Special precautions for storage
Store at room temperature below 25°C.

6.5 Nature and contents of container
DEPORES FREE is packaged in an opaque white, low-density polyethylene bottle with a dropper and a white screw cap. It is supplied in a cardboard box with 1 bottle containing 5.5 ml emulsion, and a package leaflet.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
Deva Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad.
No:1 34303 Küçükçekmece – İSTANBUL / TÜRKİYE

8. MARKETING AUTHORIZATION NUMBER
2022/125

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
Date of first authorization : 19.03.2022
Renewal of the authorization :

10. DATE OF REVISION OF THE TEXT