SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

DEPORES 0.05% Single-Dose Vial Containing Ophthalmic Emulsion
Sterile

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml emulsion contains:
Active substance:
Ciclosporin..…….0.5 mg
Excipient(s) with known effect:
Castor oil…….6.25 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ophthalmic emulsion
Preservative free, white homogenous emulsion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DEPORES 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 twice a day, approximately 12 hours apart, in each eye.

Method of administration
It is instilled into eye. Before use, the vial should be inverted a few times to obtain homogeneous, white, opaque emulsion. DEPORES can be used concomitantly with artificial tears, allowing a 15 minute interval between products. The vial should be discarded immediately after use.

Additional information on special populations
Renal/Hepatic impairment
There is no data on these populations for topical ophthalmic administration.

Pediatric population
The safety and efficacy of ophthalmic ciclosporin has not been established in children below 16 years of age.

Geriatric population
The efficacy and safety of ophthalmic ciclosporin do not differ between young and elderly patients.

4.3 Contraindications

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

4.4 Special warning and precautions for use

DEPORES is for ophthalmic use only. The emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

In order to prevent contamination of emulsion, the tip of the vial should not come into contact with the eye or any other surface.

Ciclosporin has not been studied in patients with history of herpes keratitis.

DEPORES should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of ophthalmic emulsion.

The safety and efficacy of ophthalmic ciclosporin has not been established in children below 16 years of age.

The efficacy and safety of ophthalmic ciclosporin do not differ between young and elderly patients.

No increase in bacterial or fungal ocular infections was reported following administration of ophthalmic ciclosporin.

DEPORES contains castor oil. May cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

DEPORES can be used concomitantly with artificial tears, allowing a 15 minute interval between products. Interaction between topically administered DEPORES and systemic medicines is not expected. There is not much information regarding the interaction of ophthalmic medicines used concomitantly with topical ophthalmic ciclosporin.

Additional information on special populations
There is no interaction study for specific populations.

Pediatric population:
There is no interaction study for pediatric populations.

4.6 Fertility, pregnancy and lactation

General recommendation
Pregnancy category is C.

Women of childbearing potential/Contraception
Animal studies are insufficient with respect to effects on pregnancy and/or embryonal/fetal

development and/or parturition and/or postnatal development. The potential risk for humans is unknown.

Pregnancy
DEPORES should not be used in pregnant women unless clearly necessary. If it is absolutely necessary, it should be used under the supervision of a doctor by evaluating the risk/benefit ratio on the fetus.

Lactation
It is not known whether the medicine is excreted in breast milk. Therefore, if it is absolutely necessary, it should be used under the supervision of a doctor by evaluating the risk/benefit ratio.

Reproductive ability / Fertility
No effects on human reproductive ability/fertility have been reported for topical ophthalmic use.

4.7 Effects on ability to drive and use machines

As with all ocular medicines, if transient blurred vision occurs at instillation, the patient must wait until the vision clears before driving or using machinery.

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: ocular burning
Common: conjunctival hyperemia, ocular discharge, epiphora (lacrimation), eye pain, foreign body sensation, pruritus, stinging and visual disturbance (often 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

Overdose has not been reported in humans regarding to the ophthalmic administration of ciclosporin. In case of overdose, general symptomatic and supportive treatment is instituted.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophthalmologicals
ATC code: S01XA18

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

Ciclosporin is an immunosuppressive agent when administered systemically. In patients whose tear production is presumed to be suppressed due to ocular inflammation associated with

keratoconjunctivitis sicca, ciclosporin emulsion is thought to act as a partial immunomodulator. The exact mechanism of action is not known.

5.2 Pharmacokinetic properties

General properties
Blood ciclosporin A concentrations were measured with specific high pressure liquid chromatography-mass spectrometry studies following administration of ciclosporin into the eye. Blood concentrations of ciclosporin after topical administration of ciclosporin emulsion twice daily in humans for up to 12 months, were below the quantitation limit of 0.1 ng/ml. There was no detectable medicine accumulation in blood during 12 months of treatment with ciclosporin ophthalmic emulsion.

Absorption, distribution, biotransformation and elimination data in related to ocular administration was not reported.

5.3 Preclinical safety data

Preclinical effects have been observed in systemic administration of little clinical significance, which is considered to sufficiently exceed the maximum administration in humans. No treatment-related systemic or ocular toxicity occurred. In multiple dosing, no system of drug accumulation could be detected.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Castor oil
Polysorbate 80
Carbomer 934
Glycerol
Sodium hydroxide
Water for injection

6.2 Incompatibilities

There is not any known incompatibility.

6.3 Shelf life

36 months.
After the sachets are opened, vials in sachets should be used within 28 days.
Vials are for single-use, the remaining contents should be discarded.

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

DEPORES is available as 0.4 ml emulsion in single-use vials. Each box contains a total of 30 or 50 single-use vials, as 3 or 5 peelable sachets each containing 10 single-use vials.

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 AUTHORIZATION HOLDER

DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece/İSTANBUL - TURKEY

8. MARKETING AUTHORIZATION NUMBER

2014/97

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization: 13.02.2014
Date of last renewal:

10. DATE OF REVISION OF THE TEXT

23.11.2022