



PACKAGE LEAFLET

DEPORES FREE 0.05% Eye Drops, Emulsion

Instilled into the eye.

Sterile, preservative-free.

- **Active substance:** Each 1 ml emulsion contains 0.5 mg ciclosporin.
- **Excipient(s):** Castor oil, polysorbate 80, carbomer, glycerol, sodium hydroxide, water for injection.

Read this entire LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have any further questions, please consult your doctor or pharmacist.*
- *This medicine has been prescribed for you only; do not pass it on to others.*
- *If you visit the doctor or hospital during the use of this medicine, inform them of your use of this medicine.*
- *Please exactly follow the instructions in this leaflet. Do not use **high or low** dosage other than the dose recommended to you for the medicine.*

In this leaflet:

1. ***What DEPORES FREE is and what it is used for***
2. ***What you need to know before you take DEPORES FREE***
3. ***How to use DEPORES FREE***
4. ***Possible side effects***
5. ***How to store DEPORES FREE***

1. WHAT DEPORES FREE IS AND WHAT IT IS USED FOR

DEPORES FREE is a preservative-free, white colored, homogeneous opaque eye drop emulsion without phase separation in an opaque white bottle containing 5.5 ml of emulsion.

DEPORES FREE contains cyclosporine, which has anti-inflammatory effects and regulates the immune system associated with the eye surface when dropped into the eye. No excretion or accumulation in human blood has been detected.

DEPORES FREE is used to increase tear production in patients with presumed suppression of tear production due to inflammation in the eye associated with dry eye.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEPORES FREE

DO NOT USE DEPORES FREE

If you have known or suspected allergy to any of the ingredients of this medicine, and if you have an infection associated with microorganisms on your eye, do not use this medicine.

TAKE SPECIAL CARE WITH DEPORES FREE in the following conditions

Do not instill DEPORES FREE with contact lenses on. If you are wearing contact lenses, remove them before instilling the medicine. You can re-insert your lenses 15 minutes after instilling DEPORES FREE.



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 young and old patients.

Even if such warnings were present for any period in the past, please consult your doctor.

Using DEPORES FREE with food and drinks

Since it is applied to the eye, DEPORES FREE is not expected to interact with food and beverages.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Your doctor will decide on the use of the medicine by assessing the risk/benefit ratio.

If you realize that you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Your doctor will decide on the use of the medicine by assessing the risk/benefit ratio.

Driving and using machines

If you experience eye discomfort or blurred vision after instillation of DEPORES FREE, wait until your vision becomes clear before driving or operating machinery.

Important information about some ingredients contained in DEPORES FREE

DEPORES FREE contains castor oil which may cause skin reactions.

Use with other medicines

If you need to instill more than one medicines in your eye, leave 15 minutes between instillations of two different medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or non-prescription medicines.

3. HOW TO USE DEPORES FREE

Instructions for proper use and dose/frequency of administration

Instill 1 drop of DEPORES FREE Eye Drops, Emulsion into each eye 2 times a day, approximately 12 hours apart.

Route and method of administration

Do not let the tip of the dropper touch your eyes or any surface to avoid contaminating the medicine with germs.

DEPORES FREE can be used together with artificial tears. There should be period of 15 minutes between instillations of the different ready-made medications applied into the eyes.

DEPORES FREE is for use on the eye only. Before use, invert the bottle several times to obtain a coherent, white, opaque and homogeneous emulsion without phase separation.



Figure 1



Figure 2



Figure 3



Figure 4

- DEPORES FREE is packaged as shown in figures 1 and 2.
- Open the cap by turning it (Figure 3).
- Tilt your head back, look upwards and pull your lower eyelid downwards (Figure 4).
- Hold the bottle with the tip of the dropper downwards and instill 1 drop into your lower eyelid (Figure 4).

Different age groups

Use in children

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

Use in elderly

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

Special conditions for use

Renal / Hepatic impairment

There are no specific reports of kidney/liver failure in instillation into the eye.

If you have the impression that the effect of DEPORES FREE is too strong or too weak, talk to your doctor or pharmacist.

If you use more DEPORES FREE than you should

If you have used more DEPORES FREE than you should, talk to a doctor or pharmacist.

If you forget to use DEPORES FREE

Do not take a double dose to make up for a forgotten dose.

Side effects that may occur when treatment with DEPORES FREE is stopped

There are no side effects expected when treatment with DEPORES FREE is stopped.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in patients who are sensitive to the ingredients of DEPORES FREE.

If any of the following occurs, stop taking DEPORES FREE and IMMEDIATELY inform your doctor or refer to the emergency service of the nearest hospital:

Swelling of the hands, feet, wrists, face, lips or especially swelling of the mouth or throat, which makes swallowing or breathing difficult.



These are all very serious side effects.

If you have any of these, it means that you have serious allergy to DEPORES FREE. You may need urgent medical attention or hospitalization.

All of these very serious side effects are seen rarely.

Side effects are listed below according to their frequency:

Very common: may affect at least 1 in 10 patients.

Common: may affect less than 1 in 10 patients but more than 1 in 100 patients.

Uncommon: may affect less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: may affect less than 1 in 1,000 patients.

Very rare: may affect less than 1 in 10,000 patients.

Not known: Frequency cannot be estimated from the available data.

Very common

- Burning in the eyes

Common

- Stinging in the eyes
- Eye redness
- Eye discharge
- Watery eyes
- Eye pain
- Foreign body sensation
- Itching
- Impaired vision

These are mild side effects of DEPORES FREE.

If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEPORES FREE

Keep DEPORES FREE out of reach and sight of children and in its original package.

Store at room temperature below 25°C.

After the bottle is first opened, the product should be used within 90 days. During this period, the product can be stored at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use DEPORES FREE after expiry, which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.



Marketing Authorization Holder:

DEVA HOLDİNG A.Ş.

Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturer:

Deva Holding A.Ş.

Kartepe – KOCAELİ / TÜRKİYE

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