



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### DEKORT 5 mg/5 ml Eye and Ear Drops, Solution

Instilled into the eyes and ears.

Sterile

**Active Substance:** Each ml contains dexamethasone 21-phosphate disodium equivalent to 1 mg dexamethasone 21-phosphate.

**Excipients:** Creatinine, Celite 512, Tween 80, sodium citrate dihydrate, sodium bisulfite, sodium borate decahydrate, EDTA disodium, 2-phenyl ethanol, benzalkonium chloride, purified water.

**Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

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## 1. WHAT DEKORT IS AND WHAT IT IS USED FOR

DEKORT is almost colorless to very light yellow colored clear solution with characteristic odor (phenylethyl-alcohol).

DEKORT belongs to one of the group of medicines called corticosteroids. It helps prevent or lower inflammation in the eye and ear.

DEKORT is used to treat inflammation of the ear, the surface of the eye and the front part inside the eye (anterior segment) and is used to prevent or treat inflammation after surgery. It helps reduce symptoms of inflammation such as redness, pain, and swelling.

DEKORT is supplied in a 5 mL, opaque, sterile, low-density polyethylene (LDPE) bottle with a white, sterile internal plug that functions as a dropper, sealed with a HDPE cap and a safety ring.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU USE DEKORT

### **Do not use DEKORT,**

- If you are allergic (hypersensitive) to dexamethasone, to sulfides or any of the other ingredients of DEKORT
- If you have any sudden viral infection in your cornea (transparent part in the front of the eye) or

conjunctiva (the mucous membrane that covers the front of the eye) or inflammation of the transparent membrane covering the colored part of the eye (herpes simplex keratitis)

- If you have a bacterial eye infection
- If you have any fungal disease in your eye or ear or if you have an untreated parasitic infection
- If your eardrum is perforated
- If you have cold sores (Herpes simplex virus), smallpox, chickenpox (Varicella Zoster) or other viral infections of the eye: except shingles (herpes zoster)
- If you have tuberculosis (an eye disease caused by various bacteria) in your eye

### **Take special care with DEKORT,**

- If you have had a herpes simplex infection in your eye in the past. If your condition does not improve or worsens, consult a doctor.
- If you use DEKORT a long time or very often, you may become predisposed to increased pressure within the eye, cataract development or eye infections. Your doctor may want to check our eyes regularly. This is particularly important in risk of corticosteroid-induced ocular hypertension (high intraocular pressure) in adults. DEKORT is not approved for use in pediatric patients (children). In patients with predisposing factors (eg, diabetes), the risk of increased corticosteroid-induced intraocular pressure and/or cataract formation increases.
- If you have increased pressure within the eye (glaucoma), please ask your doctor if there is a need for regular check-ups, as DEKORT can increase intraocular pressure.
- Cushing's syndrome may develop as the drug passes into your blood. If you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with DEKORT. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a drug called ritanovir.
- If you use corticosteroids, as they may conceal, trigger or worsen severe inflammatory infections of the eye.
- If you have a disorder causing a thinning of the eye tissues (cornea or sclera). Prolonged use of external corticosteroids may cause further thinning and possible perforation.
- Use this medicine as long as the doctor prescribes it to you. Do not interrupt the treatment prematurely. If your condition deteriorates or does not improve, consult your doctor. You may be more susceptible to eye infections with the use of this medicine.
- External used ophthalmic corticosteroids may make eye infections worse and delay healing of an eye wound. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Using topical NSAIDs at the same time as topical steroids may increase corneal healing problems.
- If you are using more than one sort of eye drops leave 5 minutes between applications.

*If these warnings are valid for you, even if only for a period in the past, please consult to your doctor.*

### **Using DEKORT with food and drinks**

DEKORT is used by dropping into the eye or ear. Do not use the product in any other way. If the product is used as recommended, it is not affected by foods and drinks.

### **Pregnancy**

*Consult your doctor or pharmacist before using this drug.*



There is insufficient information available of dexamethasone use in pregnant women. Potential risk towards humans is not known. DEKORT should not be used during pregnancy as long as the clinical condition of the mother does not require treatment with DEKORT.

*During your treatment, if you realize that you're pregnant, consult to your doctor or pharmacist immediately.*

### **Breastfeeding**

*Consult your doctor or pharmacist before using this drug.*

It is not known whether the topical (external) application of DEKORT results in systemic absorption and whether it passes into human milk.

When deciding whether to stop breastfeeding or whether to stop treatment or to avoid treatment, the benefit of breastfeeding for the child and the benefit of DEKORT for the breastfeeding mother should be taken into account.

### **Driving and using machines**

DEKORT may cause your vision to be blurred for some time after use. Do not drive or use any machines unless your vision is clear.

### **Important information regarding some excipients in DEKORT**

Wearing of contact lenses during treatment for eye infections must be avoided as they may worsen your condition.

The preservative in DEKORT, benzalkonium chloride may cause eye irritation and is also known to discolor soft contact lenses. If you wear contact lenses, remove contact lenses prior application of DEKORT and wait at least 15 minutes before reinsertion.

### **Taking/using other medicines**

Tell your doctor if you are using topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications). External used ophthalmic corticosteroids may make eye infections worse and delay healing of an eye wound. Topical NSAIDs (Non-Steroidal Anti Inflammatory Drugs-Medications) are also known to slow or delay healing. Using topical NSAIDs at the same time as topical steroids may increase corneal healing problems.

Tell your doctor if you are using ritonavir, as this may increase the amount of dexamethasone in the blood.

If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

*Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.*

## **3. HOW TO USE DEKORT**

### **Instructions for proper use and dose/frequency of administration**

Always use DEKORT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose for adults is 1 or 2 drops into the eye(s) every 3 to 6 hours for chronic inflammation. For serious or severe inflammation, your doctor may initially increase the dose by 1 to 2 drops into the eye(s) every 30 to 60 minutes until a positive response is received. The frequency of application will be gradually reduced until treatment is stopped.

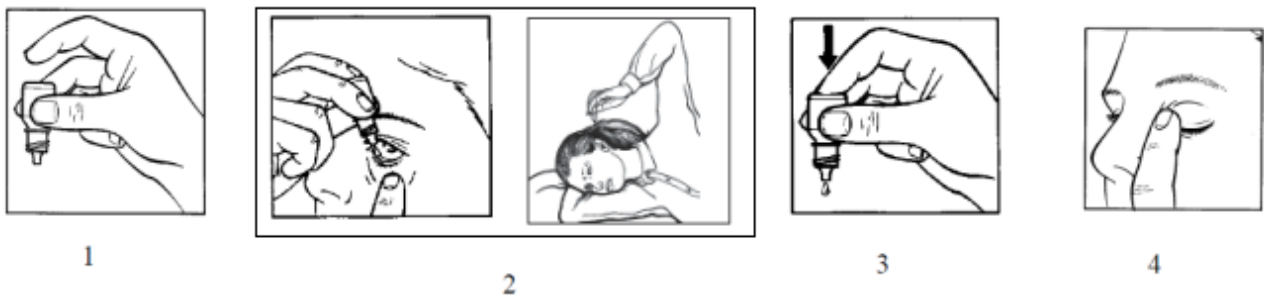
For allergies or mild inflammations, the usual dose is 1 to 2 drops in the eye(s) every 3 to 4 hours.

For application into the ear, after the ear is thoroughly cleaned and dried, 3-4 drops are instilled into the ear canal 2-3 times a day. Once a response is obtained from the treatment, the dose is gradually reduced.

In each case, your doctor will inform you about how long your treatment will continue.

Use DEKORT only for your eyes or ears. Do not use the product by any other means.

### **Method and route of administration**



1. Get the DEKORT bottle and a mirror.
2. Wash your hands.
3. Shake the bottle well.
4. Open the cap of the bottle.
5. Hold the bottle, pointing down, between your thumb and other fingers (Figure 1).
6. Tilt your head back. Pull down your lower eyelid with a clean finger until there is a “pocket” between your eyelid and your eye. The drop will go in there (Figure 2). If it is for the ear, the drop is dripped into the ear canal as in Figure 2.
7. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
8. Do not touch your eye, eyelid, surrounding areas, in or around your ears, or other surfaces with the dropper. It could infect the drops.
9. Gently press on the base of the bottle with your index finger in order to release one drop of DEKORT at a time (Figure 3).
10. After using DEKORT, release your eyelid, close your eye, place a finger on the inner corner of your eye and then press against your nose (Figure 4). This will prevent DEKORT from leaking into other parts of your body. If you are using it for the ear, wait for about 60 seconds to prevent the medicine from flowing outwards.
11. If you are to use the drops in both eyes/ears, repeat the same steps for the other eye/ear as well.
12. Put the bottle cap firmly back on immediately after use.
13. Use only one bottle at a time. (Do not open a new bottle without completely finishing the contents of the opened bottle.)

Try once more, if the drop does not fall into your eye or ear.



### **Different age groups**

#### **Use in children**

DEKORT is not recommended in children due to insufficient data on safety and/or efficacy.

DEKORT is not recommended for use in infants and young children unless absolutely required.

#### **Use in elderly**

Its use in the elderly is the same as in adults.

### **Special conditions for use**

There is no special condition for use.

*If you have the impression that the effect of DEKORT is too strong or too weak, please contact your doctor or pharmacist.*

### **If you used more DEKORT than you should**

If necessary, wash your eye(s) or ears with lukewarm water to remove DEKORT.

*Talk to a doctor or pharmacist if you have used more DEKORT than you should.*

### **If you forget to use DEKORT**

Apply a single dose when you remember. If the next application time is close, do not take the forgotten dose; continue to apply in your normal schedule.

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

### **If you stop using DEKORT**

Treatment should not be stopped before completion. Premature cessation of treatment with high doses of steroids causes regression and progression of the disease.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, side effects can occur in persons who are sensitive to the ingredients of DEKORT.

You can continue to use the medicine unless the side effects are very serious. If you are worried, talk to your doctor or pharmacist. Do not stop using DEKORT without talking to your doctor.

**If any of the following occur, stop using DEKORT and IMMEDIATELY inform your doctor or go to the nearest emergency department:**

- Hypersensitivity
- Spotting on the cornea
- Decreased visual acuity
- Drooping of the eyelid
- Eye pain
- Corneal ulcer (ulcerative keratitis)
- Corneal erosion
- Muscle weakness and wasting
- Purple stretch marks on body skin



- Increased blood pressure
- Glaucoma with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection caused by pathogens including herpes simplex, perforation (damage) to the eyeball

These are all very serious side effects.  
You may need urgent medical attention or hospitalization.

In rare cases, filtrating blebs have been reported when topical steroids were used after cataract surgery.

Stinging or burning may occur rarely.

Side effects are listed in frequencies as below:

- Very common : affects at least 1 in 10 patients
- Common : affects 1 to 10 patients in 100
- Uncommon : affects 1 to 10 patients in 1000
- Rare : affects 1 to 10 patients in 10.000
- Very rare : affects less than 1 patient in 10,000
- Unknown : cannot be estimated from the available data.

The following side effects have been reported in clinical trials with dexamethasone:

**Common**

- Discomfort in your eyes

**Uncommon**

- Taste disorders
- Inflammation (keratitis) in the transparent body (cornea) of the eye
- Inflammation of the conjunctival layer of the eye (conjunctivitis)
- Dry eye syndrome
- Corneal eye staining
- Sensitivity to light or daylight
- Blurred vision
- Itching in the eye
- Foreign body sensation in the eye
- Increase in tear production
- Abnormal sensation in the eye
- Eyelid crusting
- Eye irritation
- Eye redness

Adverse effects reported post-marketing with frequency unknown:

- Hypersensitivity
- Dizziness
- Headache
- Increased intraocular pressure
- Reduced visual acuity



- Corneal erosion
- Pain in the eye
- Increase in pupil size
- Drooping of eyelid
- Corneal ulcer (ulcerative keratitis)
- Cushing's syndrome, insufficiency in the function of the adrenal gland
- Insufficient function of the adrenal gland
- Hormone problems: growth of extra body hair (particularly in women), muscle weakness and wasting, purple stretch marks on body skin, increased blood pressure, irregular or missing periods, changes in the levels of protein and calcium in your body, stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushing's syndrome' (see chapter 2, " Take special care ")

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

*If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.*

#### 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 DEKORT**

*Keep DEKORT out of the reach and sight of children and store it in its package.*

#### **Use in accordance with the expiry date.**

*Do not use DEKORT after the expiry date, which is stated on the package.*

To avoid infections, **“The bottle must be used within 15 days after first opening.”**

Please write the date you first opened the bottle in the section below.

Date the bottle was first opened: \_\_\_\_\_

Keep the bottle tightly closed after each use.

Store below 25°C at room temperature, protected from light.

Keep the bottle in an upright position.

Do not place it in the refrigerator.

For further information about this medicinal product, please contact the Marketing Registration Holder.

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.



**DEKORT 5 mg/5 ml Eye and Ear Drops, Solution**  
**Module 1.3.1 Package Leaflet**



**Marketing Authorization Holder**

DEVA Holding A.Ş.  
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34303 Küçükçekmece - ISTANBUL/TÜRKİYE

**Manufacturer**

DEVA Holding A.Ş.  
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*This leaflet was last revised in 21/02/2020.*