



PACKAGE LEAFLET

DEKORT 8 mg/2 mL I.M./I.V. Solution for Injection
For administration into veins, muscle, joints, bursa and tendons
Sterile

Active substance: Each ampoule of 2 ml (total volume) contains 8.75 mg dexamethasone 21-phosphate disodium which is equivalent to 8 mg dexamethasone 21-phosphate.

Excipients: Creatinine, phenol, sodium citrate dihydrate, sodium hydroxide, sodium metabisulphite and water for injection.

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.*

In this leaflet:

- 1. What DEKORT is and what it is used for***
- 2. What you need to know before you use DEKORT***
- 3. How to use DEKORT***
- 4. Possible side effects***
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1. WHAT DEKORT IS AND WHAT IT IS USED FOR

DEKORT is an ampoule containing dexamethasone which belongs to a group of medicines called corticosteroids (hormone-like drugs).

DEKORT is supplied in 2 ml Type 1-glass amber colored ampoules with break ring. Each cardboard box contains 1 ampoule of 2 ml.

DEKORT contains dexamethasone as the active substance.

DEKORT is effective for the treatment of various inflammatory diseases in the body.

Dexamethasone is used to treat diseases like allergic disorders, endocrine diseases (hormone-related diseases), skin diseases, rheumatic diseases, eye (ophthalmic) diseases, blood diseases, diseases which cause edema, digestive system diseases, inflammatory connective tissue diseases, nervous system disorders or respiratory disorders.

2. What you need to know BEFORE YOU USE DEKORT

Do not use DEKORT if:

- You are allergic (hypersensitive) to dexamethasone or any of the other ingredients of DEKORT,
- You have an infection affecting the whole body,
- You need to get vaccinated, especially live vaccines (measles, rubella, mumps, chicken pox, oral polio, yellow fever, BCG tuberculosis vaccine etc.)

Take special care with DEKORT if:

- You have heart failure
- There are people who have had chicken pox or measles around you, stay away from them
- You have tuberculosis
- You have a liver or kidney problem
- You have high blood pressure or diabetes
- You have osteoporosis (thinning of the bones) or muscle weakness
- You have a digestive system or stomach problem
- You have eye disorders (with herpes virus)
- You have psychiatric disorders or epilepsy
- You have increased eye pressure (glaucoma)
- You have myasthenia gravis (a type of muscle weakness disease)
- You have gastric (peptic) ulcer
- You have migraine
- You have parasitic infection
- You have growth disorder
- You have Cushing syndrome (a type of hormonal disease accompanied by high cortisol level)
- You are going through a head trauma
- You have had stroke

If these warnings apply to you, even at any time in the past, please consult your doctor.

Taking DEKORT with food and drink

It does not interact with food and drink with regard to its method of administration.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

DEKORT should not be used during pregnancy unless necessary.

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

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

Dexamethasone passes into breast milk; therefore it should not be used during breastfeeding.

Driving and using machines

DEKORT has no effect on the ability to drive and use machines.

Important information about some of the ingredients of DEKORT

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially



'sodium- free'.

Concomitant use with other medicines

If you are taking any of the following medicines, inform your doctor before taking DEKORT:

- Medicines used to treat heart and blood disorders such as warfarin, medicines that lower high blood pressure, and diuretic
- Antibiotics such as rifampicin and rifabutin
- Medicines used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone,
- Medicines for treating pain and inflammation, such as aspirin or phenylbutazone,
- Medicines used to treat diabetes,
- Medicines used to lower high potassium levels,
- Anti-cancer drugs such as aminoglutethimide,
- Ephedrine, a medicine used to relieve nasal congestion symptoms
- Acetazolamide, a medicine used for glaucoma (increased intraocular pressure)
- Carbenoxolone, a medicine used for stomach ulcers (wounds caused by gastric acid).

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

3. HOW TO USE DEKORT

• Instructions for proper use and dose/dose frequency of administration

Your doctor will determine the dose of your medicine depending on your disease and will apply it to you.

• Route and method of administration

DEKORT ampoule is administered by your doctor into a vein or muscle.

• Different age groups

Use in children

Starting dose of DEKORT may change according to severity of the disease in children.
Starting dose range is 0.02-0.3 mg/kg/day and administered as divided into 3 or 4 doses.

Use in elderly

Caution should be exercised in dose selection in the elderly, taking into account the extreme frequency of renal, hepatic or cardiac function decline and concomitant disease, or other drug therapy, generally starting with the lower dosage range. The risk of diabetes, fluid retention and hypertension should be considered, especially in elderly patients treated with corticosteroids.

• Use in special conditions

Kidney failure:

Doses indicated above can be used.

Liver failure:

Doses indicated above can be used.

Please talk your doctor or pharmacist if you have any concerns as to whether the effect of DEKORT is too strong or weak.



If you take more DEKORT than you should

Overdose of DEKORT may cause swelling of throat, skin reaction and difficulty in breathing.
If you take more DEKORT than you should, talk to your doctor or pharmacist.

If you forget to use DEKORT

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

If you forget to take a dose, take this dose as soon as you remember and resume the usual schedule.

If you stop taking DEKORT

It may be dangerous if you suddenly stop taking this medicine. If you need to stop this treatment, follow your doctor's advice. Your doctor will gradually decrease the dose of the medicine and end it. Stopping this medicine suddenly may make your condition worse.

You may also experience withdrawal symptoms. These include fever, headache, visual impairment (pain in the eye or inflammation of the eye), feeling sick, muscle and joint pain, the lining of the nose, weight loss, itchy skin and conjunctivitis.

If you have any further questions on the use of this product, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DEKORT can cause side effects in patients with hypersensitivity to its ingredients.

If you experience a side effect, if any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Stop taking DEKORT, tell your doctor STRAIGHT AWAY or go to the emergency department of the nearest hospital if you notice any of the following side effects:

- Rash
- Itching
- Difficulty in breathing and fainting
- Angioedema (swelling of the face and throat as a result of allergy)

These are very serious side effects. If you have any of these, it means that you have serious allergy to DEKORT. You may need urgent medical attention or hospitalization.

Tell your doctor or go to the nearest hospital emergency department if you notice any of the following side effects:

- Feeling depressed (including suicidal ideation)
- Active or passive changes in mood (extreme irritability, restlessness) Feeling anxious, having sleeping problems, loss of memory
- Feeling, seeing or hearing things which do not exist
- Having frightening thoughts when alone

These are serious side effects. If you have any of these, you may need urgent medical attention. These side effects occur very rarely.

Tell your doctor if you notice any of the following side effects:

- Stomach bloating
- Nausea or vomiting
- Hiccups
- Diarrhea



- Inflammation of pancreas (causes severe pain in back or stomach)
- Problems related to blood sodium (salt) level
- Increased blood pressure
- Blood clotting
- Heart muscle problems following heart attack
- Increased blood sugar
- Thinning of the bones (osteoporosis)
- Muscle weakness
- Slow healing of body wounds
- Acne
- Glaucoma, cataract, eye infections
- Menstrual irregularity
- Slow growth in children
- Swelling of face
- Triggering of seizure or epilepsy
- Severe headache
- Fatigue
- Increased appetite or weight loss
- Edema and weight gain

These are mild side effects of DEKORT.

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. Local requirements for reporting side effects should be followed

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

5. HOW TO STORE DEKORT

Keep DEKORT out of the reach and sight of children and in its original package.

Store at room temperature below 25°C and protect from light.

Use it in accordance with the expiry date.

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

If you notice any defect on the package, do not use DEKORT.

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 Holding A.Ş.

Küçükçekmece – İstanbul / TURKEY

Manufacturing Site:

DEVA Holding A.Ş.

Kapaklı/TEKİRDAĞ/TURKEY

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