



PACKAGE LEAFLET: INFORMATION FOR THE USER

DEKORT 0.50 mg Tablets **Taken by mouth.**

Active substance: Each tablet contains 0.50 mg dexamethasone.

Excipients: Lactose monohydrate, maize (corn) starch, talc, magnesium stearate.

Read all of this PACKAGE 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.*
- *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.*
- *While you are taking this medicine, tell your doctor that you use this drug, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either **higher** or **lower** dose other than recommended to you.*

In this leaflet:

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

DEKORT is a tablet containing dexamethasone included in the group of corticosteroids.

DEKORT is available in blister packages of 10 tablets. Each cardboard box contains 20 tablets.

DEKORT contains the active substance dexamethasone.

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

Dexamethasone is used to treat diseases like allergic disorders, skin diseases, inflammatory intestinal disease, inflammation of joint, eye-related (ophthalmic) diseases, diseases related to heart and vascular system, blood diseases, muscle diseases, diseases which cause edema, digestive system diseases, nervous system disorders or respiratory disorders.

2. WHAT DO YOU NEED TO KNOW BEFORE YOU TAKE DEKORT

DO NOT USE DEKORT, if

- You are allergic (hypersensitive) to dexamethasone or any of the other ingredients of DEKORT,
- You have infection which affects your entire body,
- You need to get vaccinated, especially live vaccines (measles, rubella, mumps, chicken pox, oral infantile paralysis, yellow fever, BCG tuberculosis vaccine etc.)

TAKE SPECIAL CARE with DEKORT, if

- You have heart failure
- There are people who had chicken pox or measles around you, stay away from them.

- You have tuberculosis
- You have hepatic or renal disorder
- You have high blood pressure or diabetes (diabetes mellitus)
- You have bone loss (osteoporosis) or muscle weakness
- You have digestive system or stomach disorder
- You have eye disorder (with herpes virus)
- You have psychiatric disorders or epilepsy
- You have eye tension (glaucoma)
- You have myasthenia gravis (a type of muscle weakness disease)
- You have gastric (peptic) ulcer
- You have migraine
- You have parasite 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 had a stroke

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Taking DEKORT with food and drink

Take DEKORT after meals.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

DEKORT should not be used during pregnancy unless it is medically required.

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

Breast-Feeding

Consult your doctor or pharmacist before taking this medicine.

Dexamethasone is excreted in human milk; therefore it should not be used during breastfeeding.

Driving and using machines

DEKORT does not have any effect on ability to drive and use machines.

Important information about some of the other ingredients of DEKORT

Each DEKORT contains 150 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Taking with other medicines

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

- Drugs which are used to treat heart and blood disorders such as warfarin, drugs which lower blood pressure and diuretics (drugs that promote the production of urine)
- Antibiotics such as rifampicin and rifabutin
- Drugs used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone
- Pain killers or drugs which remove inflammation such as aspirin or phenylbutazone
- Drugs used to treat diabetes (diabetes mellitus)

- Drugs used to lower potassium levels
- Cancer drugs such as aminoglutethimide
- Ephedrine used to relieve the symptoms of nasal obstruction
- Acetazolamide used for glaucoma (increased intraocular pressure)
- Carbenoxolone used for ulcer (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 TAKE DEKORT

Instructions for proper use and dose/dose frequency

Daily dose may change between 0.75-9 mg. In mild cases, it may be decreased below 0.75 mg; in more severe cases, it may be increased over 9 mg. Daily dose should be divided into 3 or 4 sections and administered.

Administered dose may change according to clinical condition of patients.

Route and method of administration:

Do not break or chew DEKORT. Swallow it with some water.

Do not forget to take your drug on time.

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.

Maintenance dose is 0.01-0.1 mg/kg/day.

Use in elderly

Dose should be chosen carefully for an elderly patient and the treatment should be started always with the lowest dose of dose range; decreasing hepatic, renal or cardiac function frequency and concomitant disease or treatment with other drugs should be taken into consideration. Increased risk of diabetes, fluid retention and hypertension should be especially considered in elderly patients under corticosteroid treatment.

Special conditions for use

Use in kidney failure

Doses indicated above can be used.

Use in liver failure

Doses indicated above can be used.

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

If you take more DEKORT than you should

Overdose of DEKORT may cause swelling of throat, skin reaction and difficulty in breathing.



If you have taken more DEKORT than you should, talk to your doctor or pharmacist.

If you forget to take DEKORT

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

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

If you stop taking DEKORT

It may be dangerous for you to suddenly stop taking this drug. If you need to end this treatment, follow your doctor's instructions. Your doctor will end the treatment by gradually decreasing the dose. Sudden discontinuation of this treatment may aggravate your condition.

Moreover; you may experience withdrawal symptoms. These are; fever, headache, visual impairment (pain in the eye or inflammation of the eye), feeling sick, muscle and joint pain, swelling in inner section of the nose, weight loss, itching of skin and conjunctivitis.

If you have further questions about 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 one of the side effects gets aggravated or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you get any of the followings, stop taking DEKORT and contact your doctor or go to your nearest hospital emergency department IMMEDIATELY:

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

These are all very serious side effects. If you have any of these, you are severely hypersensitive (allergic) against DEKORT. You may need emergency medical intervention or hospitalization.

If you notice any of the followings, inform your doctor immediately or go to the nearest hospital emergency department:

- Depressive emotion (including the thought of suicide),
- Active or passive changes in the state of mind (extreme outburst, restlessness),
- Aggressiveness, sleeping problem, loss of memory,
- Feeling, seeing or hearing things that do not exist,
- Having dreadful thoughts when you are alone

These are all serious side effects. They require emergency medical intervention.

These side effects occur very rarely.

If you notice any of the followings inform your doctor:

- Stomach bloating
- Nausea or vomiting
- Hiccup
- Diarrhea

- Inflammation of pancreas (causes severe back or stomach pain)
- Blood salt level problems
- Increased blood pressure
- Blood clotting
- Heart muscle problems following heart attack
- Increased blood sugar
- Weakening, thinning of bones (osteoporosis)
- Muscle weakness
- Slow healing of body wounds
- Pimples
- Glaucoma, cataract, eye infections
- Menstrual irregularity
- Slowing of 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. You can also report side effects directly to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of ‘Side Effect Reporting for Medicines’ at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects you can help provide more information on the safety of this medicine.

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

5. HOW TO STORE DEKORT

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

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

Take this medicine in accordance with the expiry date.

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

If you notice any damage on the product or 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

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