PACKAGE LEAFLET

DEKORT 0.75 mg Tablets
Taken by mouth.

***Active substance*:** Each tablet contains 0.75 mg dexamethasone.
Excipients: Lactose monohydrate (from cow's milk), maize starch, talc, magnesium stearate, F.D.C. Red No:3.

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

DEKORT is a tablet containing dexamethasone included in the group of corticosteroids.
DEKORT is available in blister packs 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 allergic disorders, skin diseases, inflammatory bowel disease, joint inflammation, rheumatic disorders, eye-related (ophthalmic) disorders, diseases related to heart and vascular system, blood disorders, muscle diseases, diseases that 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 hypersensitive to dexamethasone or any of the other ingredients of DEKORT,
- You have infection that affects your entire body,
- You need to get vaccinated, especially live vaccines (measles, rubella, mumps, chickenpox, oral polio, yellow fever, BGC tuberculosis vaccine etc.)

TAKE SPECIAL CARE with DEKORT, if:
- You have heart failure
- There are people around you who had chickenpox or measles, stay away from them.
- You have tuberculosis

- You have liver or kidney problems
- You have high blood pressure or diabetes (diabetes mellitus)
- You have bone loss (osteoporosis) or muscle weakness
- You have digestive system or stomach problems
- You have an 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 stomach (peptic) ulcers
- You suffer from migraine
- You have a parasitic infection
- You have a growth disorder
- You have Cushing's syndrome (a hormonal disease accompanied by high cortisol levels)
- You are going through a head trauma
- You had a stroke

Please consult your doctor if these warnings apply to you, even 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 you are pregnant during treatment, tell your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist 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 driving and using machines.

Important information about some of the other ingredients of DEKORT
Each DEKORT 0.75 mg tablet 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 medicinal product.

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 (water pills)
- Antibiotics such as rifampicin and rifabutin
- Drugs used to treat epilepsy e.g. phenytoin, carbamazepine, phenobarbitone, or primidone
- Painkillers or anti-inflammatory drugs 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 stuffiness in the nose
- Acetazolamide, used for glaucoma (increased intraocular pressure)
- Carbenoxolone, used for ulcers (sores caused by stomach 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

The starting dose may vary between 0.75 to 9 mg daily. The dose may be lower than 0.75 mg in mild cases, and may exceed 9 mg in more severe cases. The daily dose should be divided into 3 or 4 doses. The dosage may differ depending on the clinical condition of the patients.

Route and method of administration

Do not break or chew DEKORT; swallow it with some water.
Do not forget to take your medication on time.

Different age groups

Use in children

The initial dose of DEKORT in children may change according to severity of the disease.
The initial dose range is 0.02 to 0.3 mg/kg/day and given as divided into 3 or 4 doses.
The maintenance dose is 0.01 to 0.1 mg/kg/day.

Use in elderly

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased liver, kidney, or heart function, and of concomitant disease or other drug therapy. In particular, the increased risk of diabetes mellitus, fluid retention and hypertension in elderly patients treated with corticosteroids should be considered.

Special conditions for use

Use in kidney failure

The doses mentioned above can be used.

Use in liver failure

The doses mentioned above can be used.

If you have an impression that the effect of DEKORT 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 forget to take a dose, take it 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 could be dangerous if you suddenly stop taking this medicine. If you need to stop this treatment, follow your doctor's advice. Your doctor will stop the treatment by gradually decreasing the dose. Sudden discontinuation of this treatment may aggravate your condition. Moreover, you may experience withdrawal symptoms. These include fever, headache, visual impairment (pain in the eye or inflammation of the eye), feeling sick, muscle and joint pain, swelling in the inner section of the nose, weight loss, itching of the 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 people sensitive to its ingredients.
Please tell your doctor or pharmacist 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.

If you get any of the followings, stop taking DEKORT and IMMEDIATELY contact your doctor or go to your nearest hospital emergency department:
- Rash
- Itching
- Difficulty in breathing or fainting
- Angioedema (swelling of the face and throat as a result of allergy)

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

If you notice any of the followings, immediately inform your doctor 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 may require emergency medical intervention. These side effects occur very rarely.

If you realize 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 via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

In case you encounter any side effects not listed in this leaflet, 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.
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
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site
DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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