



## PACKAGE LEAFLET

### DEKORT 4 mg Tablets

Taken by mouth.

- **Active substance:** Each tablet contains 4 mg dexamethasone.
- **Other ingredients:** Lactose monohydrate (cow or bovine source), maize starch, microcrystalline cellulose (Type 102), crospovidone, FD&C red no.3, iron oxide yellow, 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 medicine, 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.*

#### **This leaflet includes the following headings:**

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

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

DEKORT is a tablet containing dexamethasone, which belongs to a group of medicines called corticosteroids. It is presented in packages of 20 tablets, each tablet containing 4 mg dexamethasone.

Lactose monohydrate, which is an excipient contained in DEKORT, is of cow or bovine origin.

Corticosteroids are found naturally in your body that help to keep you healthy and well.

Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body.

Dexamethasone lowers inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

DEKORT is used for the following diseases:

- Severe allergy cases (hypersensitivity reactions, allergic rhinitis, etc.)
- Skin diseases that respond to corticosteroids as deemed appropriate by the physician
- Hormonal diseases (primary and secondary adrenocortical insufficiencies, etc.)
- Blood diseases (such as hemolytic anemia [causing a decrease in red blood cells, pale yellowing of the skin, weakness and shortness of breath]; or idiopathic thrombocytopenic purpura, etc.)



- Cancer (for temporary treatment of leukemia [blood cancer] and lymphoma [lymph cancer]), acute lymphoblastic leukemia (a type of blood and bone marrow cancer), symptomatic treatment of multiple myeloma (a type of cancer that affects plasma cells of the immune system), Hodgkin's disease [a type of lymph cancer], and non-Hodgkin's lymphoma in combination with other medicinal products)
- Nervous system diseases (brain tumor, cerebral edema etc.)
- Eye diseases (eye inflammations that do not respond to topical corticosteroids)
- Respiratory diseases (asthmatic attack, croup)
- Systemic rheumatic and autoimmune diseases (caused by the immune system attacking its own tissues) (rheumatic diseases affecting internal organs, such as Lupus); and severe, progressive active rheumatoid arthritis (e.g., when there are forms that cause rapidly progressive joint damage and/or when it progresses with extra-articular findings); systemic vasculitis (inflammation of the blood vessels) such as polyarteritis nodosa; juvenile idiopathic arthritis (childhood rheumatism); rheumatoid arthritis
- Alone or in combination for the treatment and prevention of chemotherapy-induced nausea and vomiting
- Trichinosis (infection caused by the trichinella parasite) associated with the nervous system or heart muscle
- Tuberculous meningitis in conjunction with anti-infective therapy only (with appropriate chemotherapy)
- Sarcoidosis, an immune disease that can cause excess calcium and vitamin D levels in the body
- Inflammation of the heart related to a heart attack or heart surgery
- Intestinal diseases, e.g. Crohn's disease, ulcerative colitis
- Certain inflammatory skin and muscle disorders
- Palliative treatment (a set of treatment methods aimed at improving the quality of life) of neoplastic diseases (cancer)

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DEKORT**

### **Do not take DEKORT**

- If you are allergic to dexamethasone or any of the other ingredients of DEKORT,
- If you have an infection that affects the whole body (unless you are receiving treatment),
- If you have a stomach or duodenal ulcer,
- If you are going to have a vaccination by live vaccines,
- If you have a fungal infection that affects the entire body (e.g. thrush).

### **Warnings and Precautions**

Talk to your doctor or pharmacist before taking DEKORT:

- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like DEKORT.
- If any of your close family has had these illnesses.
- If you have symptoms of tumor lysis syndrome such as muscle cramping, muscle weakness, confusion, vision loss or disturbances and shortness of breath. If you have a hematological malignancy.

### **Mental health problems can happen while taking DEKORT**

(Read the "Possible Side Effects" section below)

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting the medicine.



- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

**Talk to your doctor before taking this medicine, additional monitoring may be required:**

- If you have kidney or liver problems (liver cirrhosis or chronic liver failure)
- If you have symptoms of tumor lysis syndrome such as muscle cramping, muscle weakness, confusion, vision loss or disturbances and shortness of breath, in case you suffer from hematological malignancy.
- If you have a tumor of the adrenal gland (pheochromocytoma),
- If you have high blood pressure, heart disease or you have recently had a heart attack (myocardial rupture has been reported),
- If you have diabetes or there is a family history of diabetes, your doctor may need to increase your dose of diabetic medication.
- If you have osteoporosis (thinning of the bones), particularly if you are a female who has been through the menopause,
- If you have suffered from muscle weakness with this or other steroids in the past,
- If you have glaucoma (raised eye pressure) or there is a family history of glaucoma, cataract (clouding of the lens in the eye leading to a decrease in vision),
- If you have myasthenia gravis (a condition causing weak muscles),
- If you have a bowel disorder or a stomach (peptic) ulcer,
- If you have psychiatric problems or you have had a psychiatric illness which was made worse by this type of medicine,
- If you have epilepsy (condition where you have repeated numbness or convulsions),
- If you have migraine,
- If you have an underactive thyroid gland,
- If you have a parasitic infection,
- If you have tuberculosis, septicemia or a fungal infection in the eye,
- If you have cerebral malaria (affecting the brain),
- If you have herpes (cold sores or genital herpes and ocular herpes simplex because of possible corneal perforation),
- If you have asthma,
- If you are treated for a blockage of blood vessels by blood clots (thromboembolism),
- If you have corneal ulcerations and corneal injuries.

Treatment with corticosteroid may reduce your body's ability to fight infection. This can sometimes lead to infections caused by germs that rarely cause infection under normal circumstances (called opportunistic infections). If you get an infection of any kind during treatment with this medicine, contact your doctor immediately. This is particularly important if you notice signs of pneumonia: cough, fever, shortness of breath and chest pain. You may also feel confused, particularly if you are elderly.

You should also tell your doctor if you have had tuberculosis or if you have stayed in regions, where roundworm infections are common.



It is important that whilst you are taking this medicine you avoid contact with anybody who has chickenpox, shingles or measles. These infections become more serious during treatment with steroids. If you think you may have had exposure to any of these diseases, you should consult your doctor immediately. Additionally, if you have not had any infectious diseases such as measles or chickenpox and have not received any vaccinations, you should inform your doctor by avoiding contact with people who have these diseases. Do not stop taking DEKORT.

Treatment with this medicine may cause central serous chorioretinopathy, an eye disease that leads to blurred or distorted vision. This happens usually in one of the eyes. If you notice blurring or other visual disturbances that lasts for several days, please contact your doctor.

Treatment with this medicine may cause tendon inflammation. In extremely rare cases, a tendon may rupture. This risk is increased by treatment with certain antibiotics and by kidney problems. Contact your doctor if you notice painful, stiff or swollen joints or tendons.

Treatment with DEKORT can cause a condition called adrenocortical insufficiency. This can cause change in effectiveness of the medicine following stress and trauma, surgery, childbirth or illness and your body may not be able to respond in the usual way to severe stress such as accidents, surgery, childbirth or illness.

If you have an accident, are ill, have other specific physical stress conditions, or require any surgery (even at the dentists) or you require a vaccination (particularly with 'live virus' vaccines) whilst taking or when you have finished taking DEKORT, you should inform the person treating you that you are taking or have taken steroids.

If you have suppression tests (test for the amount of hormone in the body), skin test for allergy or test for bacterial infection you should inform the person performing the test that you are taking DEKORT as it may interfere with the results.

You may also find that your doctor will reduce the amount of salt in your diet and give you a potassium supplement whilst you are taking this medicine.

### **Elderly**

If you are elderly, some of the side effects of this medicine may be more serious, especially thinning of the bones (osteoporosis), high blood pressure, low potassium levels, diabetes, susceptibility to infection and thinning of the skin. Your doctor will monitor you more closely.

### **Children**

Long-term use of high doses of steroids may cause slowed growth in children. If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals and the dose may be reduced if any effects are observed. DEKORT should not be routinely used in preterm newborns with breathing problems.

### **Using DEKORT with food and drink**

The tablets should be taken with or after food to minimize irritation to the gastrointestinal tract. Eating small, frequent meals is recommended, and possibly taking of antacids, if recommended by your doctor.

Swallow DEKORT without chewing, with some water, on a full stomach, preferably after breakfast. Drinks containing alcohol or caffeine should be avoided.



### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- DEKORT should be prescribed during pregnancy and particularly in the first trimester only if the benefit outweighs the risks for the mother and child. If you become pregnant during the use of the product, do not stop using DEKORT, but tell your doctor immediately that you are pregnant.
- Steroids may affect sperm count and motility in men.

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

### **Breast-feeding**

*Consult your doctor or pharmacist before taking this medicine.*

- Corticosteroids may pass into breast milk. A risk to the newborns/infants cannot be excluded. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with DEKORT should be made taking into account the benefit of breast-feeding to the child and the benefit of DEKORT therapy to the woman.

### **Driving and using machines**

Do not drive, use any tools or machines or carry out any hazardous tasks if you experience side effects, such as confusion, hallucinations, dizziness, tiredness, sleepiness, fainting or blurred vision.

### **Important information about some of the ingredients of DEKORT**

DEKORT contains lactose monohydrate (cow or bovine source). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **Taking other medicines**

Inform your doctor before using DEKORT if you are using any of the following medications:

- Anticoagulant medicines that thin the blood (e.g. warfarin)
- Acetylsalicylic acid or similar (Non-Steroidal Anti-Inflammatory drugs) e.g. indomethacin
- Medicines used to treat diabetes, including insulin; your doctor may need to increase your diabetic treatment dose.
- Medicines used to treat high blood pressure
- Medicines used to treat cardiac diseases
- Diuretics (water tablets)
- Amphotericin B injection
- Phenytoin, carbamazepine, primidone (epilepsy medication)
- Rifabutin, rifampicin, isoniazid (antibiotics used to treat tuberculosis)
- Antacids – particularly those containing magnesium trisilicate
- Barbiturates (medicines to help sleep and reduce distress [anxiety] and to treat epilepsy)
- Aminoglutethimide (anti-cancer treatment)
- Carbenoxolone (used in the treatment of stomach ulcers)
- Ephedrine (nasal decongestant)
- Acetazolamide (used for glaucoma and epilepsy)
- Hydrocortisone, cortisone and other corticosteroids
- Ketoconazole, itraconazole (for fungal infections)
- Ritonavir (for HIV)

- Antibiotics including erythromycin, fluoroquinolones
- Medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- Colestyramine (for high cholesterol levels)
- Estrogen hormones including the contraceptive pill
- Tetracosactide used in the test for adrenocortical function
- Sultopride used to calm emotions
- Ciclosporin used to prevent rejection after transplants
- Thalidomide (used in the treatment of multiple myeloma)
- Praziquantel given for certain worm infections
- Vaccination with live vaccines
- Chloroquine, hydroxychloroquine and mefloquine (for malaria)
- Somatotropin
- Protirelin
- Indomethacin (may interfere with dexamethasone tests for certain diseases)

Some medicines may increase the effects of DEKORT tablets and your doctor may want to monitor you carefully if you are taking these medicines (including some medicines used for HIV: ritonavir, cobicistat).

**You may be at high risk for serious side effects if you take DEKORT with these medicines:**

- Acetylsalicylic acid or similar (Non-Steroidal Anti- Inflammatory drugs) e.g. indomethacin
- Medicines used to treat diabetes
- Medicines used to treat cardiac diseases
- Diuretics (water tablets)
- Amphotericin B injection
- Acetazolamide (used for glaucoma and epilepsy)
- Tetracosactide used in the test for adrenocortical function
- Carbenoxolone (used in the treatment of stomach ulcers)
- Chloroquine, hydroxychloroquine and mefloquine (for malaria)
- Medicines used to treat high blood pressure
- Thalidomide (used in the treatment of multiple myeloma)
- Vaccination with live vaccines
- Medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- Antibiotics including fluoroquinolones

**You must read the package leaflets of all medicinal products to be taken in combination with DEKORT for information related to these medicines before starting treatment with DEKORT. When thalidomide, lenalidomide or pomalidomide is used, particular attention to pregnancy testing and prevention requirements is needed.**

*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/frequency of administration**

DEKORT dosage is adjusted according to the severity of the disease and the patient's response to treatment.



Dexamethasone is given in usual doses of 0.5 to 10 mg daily, depending on the disease being treated. In more severe disease conditions, doses above 10 mg per day may be required. The dose should be titrated to the individual patient response and disease severity. In order to minimize side effects, the lowest effective possible dose should be used.

If not given otherwise, the following doses are recommended:

Cerebral edema: The starting dose and duration of the treatment depending on the cause and severity is 6-16 mg/day (up to 24 mg) taken orally in 3-4 divided doses.

Acute asthma in adults: 16 mg/day for 2 days.

Acute skin diseases: Depending on the severity and nature of the disease, daily doses are 8-40 mg, in some cases up to 100 mg, and should be followed by dose reduction according to clinical needs.

Active phase of rheumatic diseases: Systemic lupus erythematosus, 6-16 mg/day.

Highly active rheumatoid arthritis: 12-16 mg/day in rapidly destructive forms, 6-12 mg/day with an extra-articular clinical picture.

Idiopathic thrombocytopenic purpura: 40 mg in cycles for 4 days.

Tuberculous meningitis: In patients with grade II or III disease receiving 4 weeks of intravenous therapy (0.4 mg/day per kilogram in the 1<sup>st</sup> week, 0.3 mg/day per kilogram in the 2<sup>nd</sup> week, 0.2 mg/day per kilogram in the 3<sup>rd</sup> week and 0.1 mg/day per kilogram in the 4<sup>th</sup> week) followed by 4 weeks of oral therapy, the treatment is started with a total of 4 mg per day and the dose is reduced by 1 mg each week. Patients with grade I disease receive 2 weeks of intravenous therapy (0.3 mg/day per kilogram in the 1<sup>st</sup> week and 0.2 mg/day per kilogram in the 2<sup>nd</sup> week) followed by 4 weeks of oral therapy (0.1 mg/day per kilogram for 3 weeks, then a total of 3 mg/day, decreasing by 1 mg each week).

Palliative treatment of neoplastic diseases: The starting dose and duration of the treatment depending on the cause and severity is 3-20 mg/day. Very high doses up to 96 mg can also be used for palliative treatment. Low dose combination forms (4 mg and 8 mg) and high dose forms (20 mg or 40 mg) can be used for proper dosing and reducing the number of tablets.

Treatment and prophylaxis of nausea induced by cytotoxic, emetogenic chemotherapy together with antiemetic therapy: 8-20 mg DEKORT before chemotherapy, then 4-16 mg/day on the 2<sup>nd</sup> and 3<sup>rd</sup> days.

Treatment and prevention of post-operative vomiting together with antiemetic therapy: A single dose of 8 mg before the surgical procedure.

Symptomatic treatment of multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin lymphoma in combination with other medicinal products: The usual dose is 40 mg or 20 mg once daily.

In order to reduce the undesirable effects, the following treatment rules should be observed and the lowest dose adequate for the treatment should be applied.

Although there is no harm in using high doses of glucocorticoids for a short time (up to 10 days) in some emergency situations (e.g. acute cerebral edema, anaphylactic shock, status asthmaticus, acute



transplant rejection reaction, or increasing the dose up to 1.0 g prednisolone), the high dose given at the beginning of the treatment (usually 40–80 mg) should be reduced to the maintenance dose (provided that it is less than 2 times the Cushing threshold dose) in a short time.

The maintenance treatment should be applied every other day (by extending it over twenty-four hours).

It would be appropriate to give the entire dose to the patient before 8 o'clock in the morning, so that the secretory rhythm of the adrenal glands is not affected.

A more appropriate option is to give the dose alternately every 2 days.

The treatment should not be stopped suddenly after a long-term treatment. Instead, a gradual discontinuation for the medication is recommended.

Since adrenal gland insufficiency may occur during exertion due to adrenal gland disorder, a new additional dose must be given (dose/day equivalent to 5 mg prednisolone) in these cases (e.g. trauma, surgery).

Sometimes it may be necessary to have blood or urine tests to calculate how much dose to take.

#### Long-term treatment

For the long-term treatment of several conditions, after initial therapy, glucocorticoid treatment should be switched from dexamethasone to prednisone/prednisolone to reduce suppression on the function of the adrenal cortex.

You may be given a blue card for steroid treatment: keep it with you at all times and show it to any doctor, pharmacist or nurse who treats you.

See your doctor if you develop any new infection while taking these tablets.

Long-term use may lead to eye problems such as cataracts or glaucoma. After stopping long-term treatment with DEKORT, withdrawal symptoms such as fever, weakness or pain of the muscles, joint pain or weakness (feeling sick) may occur.

Do not stop taking DEKORT abruptly. Once you no longer need it, your daily dose should be reduced gradually. However, you should talk to your doctor or pharmacist about the most appropriate way to reduce your daily dose safely.

#### **Route and method of administration**

It is taken orally.

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

Do not forget to take your medicine on time.

#### **Different age groups**

##### **Use in children**

- If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals.
- The doctor will determine the dose depending on the condition to be treated and your child's size.





### **Use in elderly**

The dosage determined for adults is applied.

### **Special conditions**

#### **Kidney failure**

The dosage mentioned above can be used.

#### **Liver failure**

The dosage mentioned above can be used.

*If you think that the effect of DEKORT is too strong or too weak, talk to your doctor or pharmacist.*

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

*If you have used more DEKORT than you should, talk to a doctor or pharmacist.*

Taking too much DEKORT can cause serious consequences, including swelling of the throat, skin reaction, difficulty breathing, and even death. Even if you feel well, go to the nearest healthcare unit with the box of medicine.

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

If you forget to take a dose, take it as soon as you remember and then continue as scheduled. Do not take a double dose to make up for forgotten doses.

### **Effects that may occur when treatment with DEKORT is stopped**

If you have been thinking about stopping the treatment with DEKORT, consult your doctor first. Do not stop this medication on your own, as it needs to be gradually lowered and then stopped.

The symptoms that have been reported when treatment has been stopped too quickly have included low blood pressure and in some cases, relapse of the disease for which the treatment was given. A 'withdrawal syndrome' may also occur which includes fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, itchy skin and inflammation of the eye (conjunctivitis). If you stop treatment too soon and some of the mentioned symptoms occur, you must talk to your doctor as soon as possible.

If you have any further questions on the use of this medicine, ask your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, DEKORT can cause side effects in patients who are sensitive to its ingredients.

Tell a doctor straight away if you experience serious mental health problems. They can affect about 5 in every 100 people taking medicines like DEKORT. These problems include:

- Feeling depressed, including thinking about suicide
- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
- Feeling, seeing or hearing things that do not exist
- Having strange and scary thoughts, changing how you act or having feelings of being alone

### **Tell a doctor straight away if you experience:**

- An allergic reaction to the medicine, including serious, potentially life-threatening allergic reactions (swelling of the throat, tongue and face, and in severe cases, difficulty in breathing and

swallowing, or dizziness), severe itching of the skin with red rashes or blisters, severe abdominal pains, nausea, vomiting, diarrhea, profound muscle weakness and fatigue, extremely low blood pressure, weight loss and fever as these may be signs of adrenocortical insufficiency

- Sudden abdominal pain, tenderness, nausea, vomiting, fever and blood in stool as these may be signs of tearing of the bowel particularly if you have or have had a bowel disease

This medicine may worsen your existing heart problem. If you experience shortness of breath or ankle swelling, consult your doctor straight away.

Other side effects:

Side effects are classified as follows:

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

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

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

Rare : may occur in less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

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

Not known : cannot be estimated from the available data.

**Not known:**

- Greater chance of picking up infections, including viral and fungal infections (e.g. thrush; recurrence of tuberculosis or some other infections, e.g. eye infections if you have already had it)
- Reduction in the number of white blood cells or increased number of white blood cells, abnormal coagulation
- Impairment of the body's regulation of hormones, swelling and weight gain of the body, full-moon face (Cushingoid state), change in effectiveness of endocrines following stress and trauma, surgery, childbirth or illness, your body may not be able to respond in the usual way to severe stress such as accidents, surgery, childbirth or illness, stunted growth in children and teenagers, irregular and absence of menstrual cycles (periods), development of excess body hair (particularly in women)
- Weight gain, loss of protein and calcium balance, increased appetite, salt imbalances, water retention in the body, potassium loss that can cause rhythm disorder; increased requirement for diabetic medication, unknown diabetes becomes evident, high levels of cholesterol and triglycerides in the blood (hypercholesterolemia and hypertriglyceridemia)
- Extreme mood swings, schizophrenia (mental disorder) may become worse, depression, inability to sleep
- Severe unusual headache with visual disturbances linked with the withdrawal of treatment, fits and worsening of epilepsy, dizziness
- Increased pressure in the eye, papilledema, thinning of the eye membranes, increased risk of viral, fungal and bacterial eye infections, worsening of symptoms associated with corneal ulcers, worsening of existing eye infections, exophthalmos (protrusion of the eyeballs), visual disturbances, cataracts, loss of vision
- Congestive heart failure in susceptible people, cardiac muscle rupture after a recent heart attack, cardiac decompensation
- High blood pressure, blood clots: formation of blood clots that may clog blood vessels for example in legs or lungs (thromboembolic complications)
- Hiccups
- Nausea, vomiting, stomach discomfort and swollen abdomen, inflammation and ulcers in the esophagus, peptic ulcers that may split and bleed, inflamed pancreas (which may show as pain in the back and abdomen), flatulence, esophageal candidiasis

- Thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, skin redness, swelling, thinning of the hair, unusual fat deposits, excessive hair growth, water retaining in the body, pigment disorders, weakened capillaries that rupture easily, observed as bleeding under the skin (increased capillary fragility), skin irritation around the mouth (perioral dermatitis)
- Thinning of the bone with an increased risk of fractures (osteoporosis), bone necrosis, tendinitis (tendon inflammation), ruptured tendons, muscle wasting, myopathy (muscle disease), muscle weakness, early stoppage of bone growth (premature epiphyseal closure)
- Changes to the number and movement of sperm, impotence
- Impaired reaction to vaccination and skin tests, slow wound healing, discomfort, malaise
- A ‘withdrawal syndrome’ may also occur which includes fever, muscle and joint pain, rhinitis, weight loss, painful itchy skin nodules and inflammation of the eye (conjunctivitis)

#### 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.

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

#### **5. HOW TO STORE DEKORT**

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

Store at room temperature below 25°C. Keep it in its original package and protected from light.

**Use this medicine in accordance with the expiry date.**

Do not use DEKORT after the expiry date stated on the package; use it before this date.

*Do not use DEKORT if you notice any defects in the product and/or on its 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 Holding A.Ş.  
Küçükçekmece - İSTANBUL/TÜRKİYE

#### ***Manufacturing Site:***

DEVA Holding A.Ş.  
Kapaklı - TEKİRDAĞ/TÜRKİYE

*This package leaflet was approved on 05/06/2023.*