**PATIENT INFORMATION LEAFLET**

**DEKSAMET 8 mg/2mL Solution for Injection**

**For intramuscular and intravenous administration.**

- ***Active substance:*** Each 2 ml ampoule contains dexamethasone sodium phosphate equivalent to 8 mg dexamethasone phosphate.
- ***Excipients:*** Creatinine 16 mg, sodium citrate 20 mg, sodium metabisulphite 2 mg, methyl paraben 3 mg, propyl paraben 0.4 mg and water for injection q.s.

**Read all of this 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high** or **low** doses other than the recommended dosage.*

**What is in this leaflet**:



**Headings are included.**

## 1. What DEKSAMET is and what it is used for?

DEKSAMET is an ampoule containing dexamethasone, a drug that belongs to the corticosteroid (drugs similar to hormones) group.

DEKSAMET is available in Type I glass amber colored ampoules of 2 ml. Each carton box is contained in boxes containing 1, 5, 50 and 100 pieces of 2 ml ampoules.

DEXAMET contains dexamethasone drug substance.

DEKSAMET is effective in the treatment of various inflammation-related diseases in the body.

Dexamethasone is used in the treatment of allergic disorders, endocrine disorders (hormonal disorders), skin disorders, rheumatic disorders, eye-related (ophthalmic) disorders, and blood disorders, disorders that cause edema, disorders of the digestive system, inflammatory connective tissue disorders, nervous system disorders or respiratory disorders.

## 2. What you need to know before you use DEKSAMET

**DO NOT USE DEKSAMET;**

If;

- You are hypersensitive to dexamethasone or any of the ingredients of DEKSAMET.
- You have an infection that affects your whole body
- You need vaccinations, especially live vaccines (measles, rubella, mumps, chickenpox, oral polio, yellow fever, BGC tuberculosis vaccine, etc.)

**USE DEKSAMET CAREFULLY;**

If;

- You have heart failure
- Stay away if there are people around you who have had chickenpox or measles
- You have tuberculosis disease
- You have liver or kidney problems
- You have high blood pressure or diabetes
- You have osteoporosis or muscle weakness
- You have a digestive system or stomach problem
- You have an eye disorder (with the herpes virus)
- You have psychiatric problems or epilepsy disease
- You have eye pressure (glaucoma)
- You have myasthenia gravis disease (a type of muscle weakness disease)
- You have a stomach (peptic) ulcer
- You have migraine
- You have a parasite infection
- You have a growth disorder
- You have Cushing's syndrome (a type of hormonal disease with high cortisol levels)
- You have a head injury
- You have had a stroke

If these warnings are valid for you, even at any time in the past, please consult your doctor.

**Use of DEKSAMET with food and drink**

There is no interaction with food and drinks in terms of administration method.

**Pregnancy**

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

DEKSAMET should not be used during pregnancy unless necessary.

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

**Breast-feeding**

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

Dexamethasone passes into breast milk, so it should not be used during breastfeeding.

**Driving and using machines**

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

**Important information about some excipients found in the composition of DEKSAMET**

This medicinal product contains less than 1 mmol (23 mg) sodium per dose, in other words, it is considered essentially free of sodium.

**Use with other medicines**

If you are using any of the following drugs, inform your doctor before using DEKSAMET:

- Medicines such as warfarin, medicines that lower blood pressure and diuretics (diuretics) used in the treatment of heart and blood disorders
- Antibiotics such as rifampicin and rifabutin
- Medicines used in the treatment of epilepsy such as phenytoin carbamazepine phenobarbitone and primidone
- Pain relievers or anti-inflammatory drugs such as aspirin or phenylbutazone
- Drugs used in the treatment of diabetes
- Medicines used to lower potassium levels
- Cancer drugs such as Aminoglutethimide
- Ephedrine used to relieve stuffy nose symptoms
- Acetazolamide used for glaucoma (increased intraocular pressure)

- Carbenoxolone used for ulcers (wounds caused by stomach acid)

*If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.*

## 3. How to use DEKSAMET

**Instructions for appropriate use and dose/administration frequency:**

Your doctor will determine the dose of the drug depending on your illness and which will be administered to you.

**Method of administration:**

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

**• Different age groups:**

**Pediatric use:**

The starting dose of DEKSAMET in children may vary depending on the condition of the disease. The starting dose is 0.02 - 0.3 mg/kg/day and is given in 3 or 4 portions.

**Geriatric Use:**

Care should be taken in dose selection in the elderly, usually starting from the lower dosage range, taking into account the excessive frequency of renal, hepatic or cardiac dysfunction and concomitant disease or other drug therapy. The risk of diabetes, fluid retention and hypertension should be considered, especially in elderly patients treated with corticosteroids.

**Special use cases:**

**Renal impairment:**

The above-mentioned doses can be used.

**Hepatic impairment**

The above-mentioned doses can be used.

*Talk to your doctor or pharmacist if you have the impression that the effect of DEKSAMET is too strong or weak.*

**If you have used more DEKSAMET than you should**

With taking more DEKSAMET, swelling of the throat, skin reaction, and difficulty in breathing may occur.

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

**If you forget to use DEKSAMET**

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

If you forget to take a dose, take it as soon as you remember and then continue as before.

**Effects which may occur when treatment with DEKSAMET is concluded**

It can be dangerous if you stop taking this medicine suddenly. If you need to stop this treatment, follow your doctor's advice. Your doctor will stop you by gradually reducing the dose of the drug. Stopping this medication suddenly may make your condition worse. Also, you may experience withdrawal symptoms. These include fever headache, visual disturbance (eye pain or inflammation of the eyes), feeling sick, muscle and joint pain, swelling of the inside of the nose, weight loss, skin itching and conjunctivitis.

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

## 4. What are the possible side effects?

Like all medicines, DEKSAMET may have side effects in people who are sensitive to the substances in its content.

If you experience any side effects, if one of the side effects gets worse, or if you encounter any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

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

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

These are all very serious side effects.

If you have one of these, you have a serious allergy to DEKSAMET. You may need urgent medical attention or hospitalization.

**If you notice any of the following, inform your doctor immediately or contact the**

**emergency department of your nearest hospital:**

- Depressive feeling (including suicidal thoughts)
- Active or passive mood changes (excessive excessiveness, restlessness)
- Being nervous, trouble sleeping, memory loss
- Feeling, seeing or hearing nonexistent objects
- Having frightening thoughts when alone

All these are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.

**If you notice any of the following, tell your doctor:**

- Stomach bloating
- Nausea or vomiting
- Hiccups
- Diarrhea
- Pancreatic inflammation (causes severe back or stomach pain)
- Problems with the salt level in the blood
- Increase in blood pressure
- Blood clotting
- Heart muscle problems following a heart attack
- High blood sugar
- Weakening and thinning of bones (osteoporosis)
- Muscle weakness
- Slow healing of skin wounds
- Acne
- Glaucoma, cataracts, eye infections
- Menstrual irregularity
- Slowing of growth in children
- Percentage swelling
- Seizure or epilepsy triggering
- Severe headache
- Tiredness
- Increased appetite or weight loss
- Edema and weight gain

These are mild side effects of DEKSAMET.

*If you encounter any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist.*

## 5. How to store DEKSAMET

*Keep DEKSAMET out of the sight and reach of children, and in its packaging.*

Store at room temperature below 30°C.

**Use in compliance with the expiry date.**

Do not use DEKSAMET after the expiration date stated on the packaging. Do not use DEKSAMET if you notice any damage in the product and/or its package.

***Marketing Authorization Holder:***

OSEL İlaç San. ve Tic. A.Ş.
Akbaba Mah. Maraş Caddesi No:52
34820 Beykoz/İSTANBUL
Tel : (0216) 320 45 50 (Pbx)
Fax : (0216) 320 41 45

*This patient information leaflet was approved on 02/01/2014.*

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

DEKSAMET 8 mg/2 mL Solution for Injection

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

In each 2 ml ampoule;

**Active substance:**

Contains dexamethasone sodium phosphate equivalent to 8 mg dexamethasone phosphate.

**Excipient(s):**

| | |
|---|---|
| Creatinine | 16 mg |
| Sodium citrate | 20 mg |
| Sodium metabisulfite | 2 mg |
| Methyl paraben | 3 mg |
| Propyl paraben | 0.4 mg |
| Water for injection | q.s. 2 ml |

“For the full list of excipients, see section 6.1.”

## 3. PHARMACEUTICAL FORM

2 ml ampoule solution

Almost colorless clear solution with characteristic odor

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

DEKSAMET Ampoule is used in inflammatory rheumatic and allergic cases that respond to treatment with corticosteroids.

The main diseases for which DEKSAMET ampoule is indicated are:

- Allergic diseases: Anaphylactic shock, allergic reactions caused by medication or transfusion, acute asthma, serum sickness, angioneurotic edema, laryngeal edema, acute dermatoses (DEKSAMET Ampoule should be administered before transfusion in cases where transfusion reactions are suspected).
- Rheumatic diseases: Evolving chronic polyarthritis, acute joint rheumatism, rheumatoid arthritis (including juvenile rheumatoid arthritis), psoriatic arthritis, osteoarthritis, spondylitis, synovitis, tendosynovitis, bursitis
- Endocrine disorders: Shocks that do not respond to known therapy (if adrenal insufficiency is suspected). Acute adrenal insufficiency such as Addison's disease,

adrenalectomy; congenital adrenal hyperplasia, non-suppurative thyroid, hypercalcemia associated with cancer. In acute adrenocortical insufficiency, DEKSAMET Ampoule can be added to the applied saline.

- Dermatological diseases: Psoriasis, seborrheic dermatitis, exfoliative dermatitis, pemphigus, dermatomyositis, scleroderma
- Collagen diseases: Systemic lupus erythematosus, acute rheumatic carditis. Respiratory system diseases: Acute, severe and disseminated pulmonary tuberculosis (combined with anti-tuberculosis drugs), aspiration pneumonitis, emphysema, lung granulomatosis, symptomatic sarcoidosis, Loeffler's syndrome, berylliosis
- Ophthalmic diseases: Conjunctivitis, keratitis, kerato-conjunctivitis, scleritis, episcleritis, uveitis, chorioretinitis, sympathetic ophthalmia, iritis, iridocyclitis, herpes zoster ophthalmicus (not herpes simplex), optic neuritis, retrobulbar neuritis
- Hematological disorders: Idiopathic thrombocytopenic purpura (IM administration is contraindicated), thrombocytopenia, hemolytic anemia, erythroblastopenia, congenital hypoplastic anemia
- Neoplastic diseases: Leukemia and lymphomas, Hodgkin's disease, lymphosarcoma
- Diseases causing edema: Idiopathic or nephrotic syndrome caused by lupus erythematosus
- Gastrointestinal system disorders: Ulcerative colitis, terminal ileitis
- Brain edema: Brain edema caused by primary or metastatic brain tumors, craniotomy or strokes (provided that it is applied in operation or other specific treatments). Conditions requiring intralesional administration: Keloids; localized inflammatory lesions of lichen planus, granuloma annulare, lichen simplex chronicus; psoriatic spots, discoid lupus erythematosus, Necrobiosis lipoidica diabeticorum, alopecia areata
- Other diseases: trichinosis causing neurological or myocardial symptoms. Meningitis that causes subarachnoid block or is likely to open, tuberculosis (with antituberculosis drugs), periarteritis nodosa, Chauffard-Still syndrome

## 4.2. Posology and method of administration

**Posology/administrationfrequency and duration**

4 mg dexamethasone 21-phosphate provides a therapeutic effect equivalent to that of 100 mg of hydrocortisone. Although it is usually given in doses of 4-20 mg, 80 mg per day should never be exceeded.

The dosage is usually adjusted according to the type and severity of the disease and the patient's reaction. Intravenous and intramuscular injections are recommended for acute illnesses. It

should be given after 4-5 hours as soon as the acute phase passes.

The following administartion method is recommended in acute allergic diseases.

Day one: 1 -2 ml DEKSAMET Ampoule (intramuscularly)
Second day: 2 dexamethasone tablet 0.75 mg twice a day
Third day: 2 dexamethasone tablet 0.75 mg twice a day
Fourth day: 1 dexamethasone tablet 0.75 mg twice a day
Fifth day: 1 dexamethasone tablet 0.75 mg once a day
Sixth day: 1 dexamethasone tablet 0.75 mg once a day
Seventh day: Treatment is concluded.
Eighth day: The doctor is visited.

In this way, the danger of overdosage is avoided.

Generally, the glucocorticoid dosage depends on the severity of the condition and patient response. In certain circumstances, extra dose adjustments may be necessary, for example in the event of stress.
If the desired response has not been achieved within a few days, glucocorticoid therapy should be discontinued.

Adults and Elderly
Once the disease is under control, the dose should be reduced or tapered to the lowest appropriate level, with continuous monitoring and surveillance of the patient (see section 4.4).
Substantially higher doses may be required in acute life-threatening situations (eg anaphylaxis, severe acute asthma).
Cerebral edema (adults): the first dose of 8-16 mg IV until a satisfactory result is achieved, followed by 5 mg IV or IM every 6 hours in brain surgery, these doses may be required until a few days after the operation. After that, the doses should be tapered gradually and stopped. The increase in intracranial pressure associated with brain tumors can be neutralized with continued treatment. The following doses are recommended for local treatment:

- Intra-articular: 1.6-3 mg large joints
- 0.6-0.8 mg small joints
- Intrabursal: 1.6-3 mg
- In tendon sheaths: 0.3-0.8 mg

The frequency of these injections can vary from 3-5 days to every 2-3 weeks.
Rectal drip (drip) in cases of ulcerative colitis: 4 mg diluted in 120 ml of saline

**Method of administration:**
Anatomical structure should be known very well for injection. Injections should never be made to the intervertebral juncture.
Before starting the injection, synovial fluid should be drawn to see if the needle has reached the desired location.
Although there is no need for local anesthesia, anesthetic agent can be injected into the soft tissue before intraarticular corticosteroid administration in very sensitive individuals. After the injection, the patient should not move the juncture too much.
Intraarticular injection should not be made in specific arthritis of gonococcal or tuberculotic origin.

**Additional information for special populations:**
**Renal/hepatic impairment:**
There is no specific dose adjustment for patients with kidney or liver failure.

**Pediatric population:**
In the pediatric population, the starting dose of dexamethasone may vary depending on the disease state. The starting dose range is 0.02-0.3 mg/kg/day and is given in 3 or 4 divided doses. Dose requirements are variable and may need to be changed according to individual needs. Usually 0.2 mg/kg to 0.4 mg/kg body weight per day.

**Geriatric population:**
Clinical studies conducted did not include sufficient numbers of patients from this group to determine whether patients aged 65 and over responded differently than younger subjects. No difference in response was identified between older and younger subjects in other reported clinical experiences. Generally speaking, for an elderly patient, dose selection should be made carefully, and treatment with the lowest dose of the dose range should always be initiated, considering the higher frequency of liver, kidney or heart function and concomitant disease or other medications in this group. The increased risk of diabetes mellitus fluid retention and hypertension should be taken into account, especially in elderly patients receiving corticosteroid therapy.

## 4.3. Contraindications

It is contraindicated in individuals with known hypersensitivity to the active substance of the preparation, in acute infections, in systemic fungal infections, in herpes zoster and in patients with ulcerated herpes simplex in the eye, as it involves immunological response and inflammatory reactions. Live vaccine administration is contraindicated.

## 4.4. Special warnings and special precautions for use

Side effects may occur at treatment doses. Therefore, the dose should be increased gradually. Corticosteroid use may mask the symptoms of some emerging diseases. It may cause the nitromavi - tetrazoline test used for bacterial infections to be (-).

Corticosteroids can activate latent amoebiasis. Therefore, before starting corticosteroid therapy, it should be checked whether there is a latent or active amoebiasis, and also attention should be paid to diarrhea of unknown cause.

Long-term use of corticosteroids can damage the optic nerves. Subcapsular cataracts and glaucoma can be seen as a result. Oral corticosteroids are not recommended for optic neuritis and may lead to an increase in new risky events.

Corticosteroids should not be used in active ocular herpes simplex. In some people, intraocular pressure may increase. If steroid therapy continues for more than 6 weeks, intraocular pressure should be followed.

The use of normal and high doses of hydrocortisone or cortisone may cause an increase in blood pressure, water and salt retention, and increased potassium excretion. These effects are less visible with synthetic derivatives except at high doses. Salt restriction and potassium supplementation in the diet may be required. Corticosteroids all increase calcium excretion. While water retention and potassium loss due to edema occur with the use of corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension or renal failure.

Live virus vaccines are contraindicated in immunosuppressive doses of corticosteroids. Again, the expected serum antibody response may not occur after the use of corticosteroids at these doses and the administration of inactive bacteria and virus vaccines. As with Addison's disease, the immunization procedure can be applied in patients undergoing corticosteroid replacement therapy.

Chickenpox and measles can be very serious or even fatal when seen in pediatric and adult corticosteroid patients. Particular care should be taken in pediatric and adult patients with chickenpox and measles. The contribution of the underlying and / or preceding corticosteroid

therapy to the risk is unknown. If chickenpox is caught, varicella zoster immune globulin (VZIG) may be indicated by prophylaxis. If measles is caught, treatment with immunoglobulin (IG) with prophylaxis, if chickenpox develops, treatment with antiviral agents should be considered.

Corticosteroids should be used with extreme caution in patients with suspected Strongyloides infections. Widespread lavral movement is observed with strongyloides hyperinfections in some immunosuppressive patients using corticosteroids. This is accompanied by severe enterocolitis and potentially fatal gram (-) septicemia.

In individuals with active tuberculosis, corticosteroids can be used together with an appropriate antituberculosis agent. Patients with latent tuberculosis or a corticosteroid indication with tuberculosis reactivation require a serious investigation into the reactivation of the disease. For this type of patients; If long-term corticosteroid therapy is to be applied, chemoprophylactic supplementation should be made.

Corticosteroids should not be stopped suddenly, but the treatment should be terminated by gradually reducing the dose. Otherwise, symptoms such as fever, myalgia, arthralgia and malacia may be seen accompanied by adrenal cortex insufficiency.

In patients with hypothyroidism and cirrhosis, the effect of corticosteroids is observed to be increased. Caution should be exercised in the use of corticosteroids in patients with ocular herpes simplex because of the possibility of corneal perforation.

Physical disorders can be seen with the use of corticosteroids. There may also be euphoria, insomnia, character change, severe depression, and visible psychotic manifestations. Emotional blunt or psychotic tendency may be aggravated by corticosteroid use. Caution should be exercised in using aspirin with corticosteroids in patients with hypoprothrombinemia. Steroids should be used with caution in cases of nonspecific ulcerative colitis, pyogenic inflammations, diverticulitis, new bowel anastomosis, active or latent peptic ulcer, diabetes mellitus, renal failure, hypertension, osteoporosis and myasthenia gravis. At high doses, peritoneal and gastrointestinal irritation has been observed. Fat embolism has also been reported as a complication of hypercorticonism.

It is reported that when high-dose corticosteroids are used, it would be more appropriate to take the drug after meals, and even antacid taking between meals will protect against peptic ulcer. Steroids may increase or decrease motility and the number of spermatoses in some patients. Steroids may cause exacerbation of systemic fungal infections. However, if specific antifungal treatment will be applied, glucocorticoid therapy can be started. The efficacy and safety of corticosteroids in children depends on the course of action of corticosteroids that are similar in children and adults. Published studies have been proven in pediatric patients treated for

nephrotic syndrome (patients older than 2 years), aggressive lymphoma and leukemia (patients older than 1 month).

For other indications for corticosteroid use in children such as severe asthma and wheezing; It is based on adequate and well-controlled studies in adults. As a result, the direction of the disease and its pathophysiology is considered to be the same in both populations. In children as in adults; Blood pressure, weight, height, intraocular pressure and clinical evaluation of the presence of infection, psychosocial disorder, thromboembolism, peptic ulcer, cataract and osteoporosis frequency should be carefully observed. A slowdown in growth rate may be observed in children who use corticosteroids, including corticosteroids participating in the systemic circulation.

The linear growth of children taking corticosteroids needs to be monitored. The potential growth effect of continued therapy must be weighed against the clinical benefit achieved and the availability of treatment alternatives. In children, the least effective dose should be used to minimize the potential growth effect of corticosteroids.

Clinical studies have not been conducted to investigate whether there is a difference in adults aged 65 years or older. In other reported clinical studies, no differences were found between the elderly and adults. Care should be taken in dose selection in the geriatric population, usually starting from the lower dosage range, taking into account the reduced kidney, liver or heart function and the excessive frequency of concomitant disease or other drug therapy. The risk of diabetes, fluid retention and hypertension should be considered, especially in elderly patients treated with corticosteroids.

This medicinal product contains less than 1 mmol (23 mg) sodium per dose; that is, it is considered essentially free of sodium.

**4.5. Interaction with other medicinal products and other forms of interaction**

Rifampicin, rifabutin, ephedrine, carbamzepine, phenylbutazone, phenobarbital, phenytoin, primidone and aminoglutetimide; It improves the metabolism of corticosteroids and their therapeutic effects may be reduced. The effects of anticholinesterases are antagonized by corticosteroids in myasthenia gravis. The desired effects of hypoglycemic agents (including insulin), anti-hypertensives, cardiac glycosides, and diuretics are antagonized by corticosteroids and the hypokalaemic effects of acetazolamide, loop diuretics, thiazide diuretics and carbenoxolone are enhanced. The effect of coumarin anticoagulants may be enhanced with concomitant corticosteroid therapy, and close monitoring of INR or prothrombin time may be required to avoid spontaneous bleeding. The renal clearance of salicylates is increased by corticosteroids, and steroid discontinuation may result in salicylate intoxication. Interactions

with salicylates may occur in patients with hypoprothrombinemia.

**Additional information for special populations:**

No interaction studies on special populations have been conducted.

**Pediatric population:**

No interaction studies in the pediatric population have been conducted.

## 4.6. Pregnancy and lactation

**General advice**

Pregnancy category is C.

**Women with child-bearing potential/Contraception**

Since there is insufficient data on the use of dexamethasone in pregnant women, it is recommended that women with childbearing potential apply appropriate contraception.

**Pregnancy**

As a result of the use of corticosteroids in pregnant women, there are no controlled and sufficient studies on the teratogenic effect. However, DEKSAMET Ampoule should not be used during pregnancy unless necessary. Corticosteroids can only be used under the supervision of a doctor and if the benefit to the mother is more than the harm to the fetus.

Hypoadrenalism symptoms that may arise when large amounts of corticosteroids are taken during pregnancy should be carefully monitored.

For dexamethasone 21-phosphate, there are insufficient data on its use in pregnant women. Animal studies are insufficient in terms of effects on pregnancy/and/or/embryonal/fetal development/and-or/birth/and/or/postnatal development. DEKSAMET Ampoule should not be used during pregnancy unless necessary. The potential risk for humans is unknown.

**Lactation**

Corticosteroids pass into breast milk. This situation causes undesirable effects such as suppression of growth and damage to the production of endogenous corticosteroids in the child. For this reason, it is recommended that mothers receiving pharmacological doses of corticosteroids should not breast-feed.

**Reproductive ability / Fertility**

Steroids can increase or decrease sperm count and ability to move in some patients.

### 4.7. Effects on ability to drive and use machines

DEKSAMET Ampoule has no known negative effects on driving and machine use.

### 4.8. Undesirable effects

Adverse events are listed according to system organ class and frequency as follows: Very common (> 1/10); common (> 1/100 to <1/10); uncommon (> 1/1,000 to <1/100); rare (> 1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

The following side effects have been reported for DEKSAMET Ampoule and the degree of frequency is not known (cannot be estimated from the available data).

**Immune system disorders**

Not known: Anaphylactic reactions, fatigue, aggravation or masking of infections

**Endocrine diseases**

Not known: Menstrual disorders, formation of a picture similar to Cushing's syndrome, delayed development in children, loss of secondary adrenocortical and pituitary response in stressful situations such as trauma, operation and disease, decreased carbohydrate tolerance, manifesting of latent diabetes mellitus, insulin or oral increased hypoglycemic need, hirsutism, decreased carbohydrate and glucose tolerance, hyperglycemia, glycosuria

**Metabolism and nutrition disorders**

Unknown: Negative nitrogen balance due to protein catabolism

**Nervous system disorders**

Not known: Convulsions, increased intracranial pressure and associated papillary edema

**Eye diseases**

Not known: Posterior, subcapsular cataracts, increased intraocular pressure, glaucoma, exophthalmos

**Cardiac disorders**

Not known: Congestive heart failure, thromboembolism

**Vascular diseases**

Not known: Hypertension

**Gastrointestinal Disorders**

Unknown: Peptic ulcer with risk of bleeding and perforation, especially intestinal inflammation, small and large intestine perforations, pancreatitis, abdominal distension, ulcerative esophagitis, increased liver enzyme levels, increased appetite, nausea

**Skin and subcutaneous tissue disorders**

Unknown: delay in wound healing, sensitive, thin skin formation; ecchymoses, erythema, increased sweating, burning and itching in the perineal area, allergic dermatitis (after IV administration), angioneurotic edema

**Musculoskeletal, connective tissue and bone disorders**

Unknown: Muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, compression fractures of the spine, aseptic necrosis of the femur and humerus head, pathological fractures of long bones, tendon rupture

**Kidney and urinary disorders**

Not known: sodium retention, fluid retention, potassium depletion, hypokalemic alkalosis

**General disorders and administration site conditions**

Not known: Thromboembolism, increased weight and appetite, nausea, psychic disorders

**Side effects that can only be seen with parenteral corticosteroid therapy are: Eye diseases**

Rare: Blindness

**Skin and subcutaneous tissue disorders**

Rare: Atrophy, hyper or hypo pigmentation, sterile abscess

**Musculoskeletal, connective tissue and bone disorders**

Not known: Charcot-type arthropathy following intraarticular administration.

### 4.9. Overdose

Acute reactions and deaths are uncommon with overdose of glucocorticoids. Symptoms of chronic toxicity also do not require treatment unless there is a special condition that may lead to hypersensitivity to glucocorticoids. In the presence of such a special situation, the stomach should be washed and symptomatic treatment should be applied. When hypersensitivity reactions and anaphylaxis are observed, adrenaline and aminophylline should be given and the patient should be kept in a warm and quiet environment. Dexamethasone does not have a specific antidote. The plasma half-life is about 190 minutes.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Systemic Corticosteroids.

ATC code: H02AB02

The active ingredient of DEKSAMET Ampoule, dexamethasone, is a glucocorticoid with high anti-inflammatory activity and is formed by the addition of a methyl group to the 16 states of the fluoro-prednisolone molecule. The fact that many side effects encountered in synthesized corticosteroids are less in terms of both severity and proportion with dexamethasone makes it possible to apply corticosteroid therapy in patients who cannot tolerate other corticosteroids.

Although it's anti-inflammatory antirheumatic and antiallergic effect is superior to known corticosteroids, its effect on electrolyte balance is negligibly small. Side effects such as loss of appetite, weight loss, severe headache, dizziness, muscle weakness seen during treatment with other corticosteroids are not observed in patients treated with dexamethasone, and the preparation does not cause sodium retention and potassium loss (except when used in high doses) provides great convenience in clinical practice. In addition to the fact that it does not cause water and salt retention, it also does not cause hypertension, which provides an effective treatment opportunity for most people with cardiovascular diseases.

### 5.2 Pharmacokinetic properties

**General properties**

Dexamethasone is a white or almost white crystalline powder. Slightly soluble in acetone, methanol, anhydrous ethanol or dioxane. It is slightly soluble in chloroform. Very slightly soluble in ether, practically insoluble in water.

As dexamethasone 21-phosphate disodium dissolves 3000 times more in water than

hydrocortisone, it is suitable for intramuscular, intravenous, intrasynovial injections and soft tissue infiltration.

Absorption:
Since its absorption is very rapid, in intramuscular administration, a rapid response is obtained as in intravenous administration. The effect is seen within two hours after it is injected into the joint.
When used in therapeutic doses, soft tissue injections and intrasynovial administrations do not cause hormonal effects seen in long-term corticosteroid treatments.

Distribution:
It is less bound to plasma proteins than other corticosteroids. Corticosteroids are rapidly distributed to tissues in the body.

Biotransformation:
Corticosteroids are mostly metabolized in the liver

Elimination:
Some of it is excreted from the kidneys with urine.

Linearity/nonlinear case:
No data available.

**Characteristics in patients**
Geriatric population:
Clinical studies have not been conducted to investigate whether there is a difference in adults aged 65 years or older. In other reported clinical studies, no differences were seen between the elderly and adults. Particular attention should be paid to the use of corticosteroids in elderly patients with diabetes mellitus, fluid retention, and hypertension.

Pediatric population:
The efficacy and safety of corticosteroids in the pediatric population is based on well-known aspects of corticosteroid effects as in adults.

## 5.3 Preclinical safety data

The drug substance contained in the preparation is a substance that has been used in the clinic for many years. Studies on it have been completed. Adverse effects that may be seen in relation to its use are included in the relevant sections (4.4, 4.6, 4.8, 4.9).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Creatinine

Sodium citrate

Sodium metabisulphite

Methyl paraben

Propyl paraben

Water for injection

### 6.2 Incompatibilities

It does not have any known incompatibilities.

### 6.3 Shelf life

24 months

### 6.4 Special precautions for storage

Store at room temperature below 30°C.

### 6.5 Nature and contents of container

2 ml amber colored Type I glass ampoule containing 2 ml of solution

Available in boxes containing 1, 5, 50 and 100 ampoules.

### 6.6 Instructions for use and handling and disposal

Unused products or waste materials must be disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

## 7. MARKETING AUTHORISATION HOLDER

Osel İlaç San. ve Tic. A.Ş.

Akbaba Mah. Maraş Cad. No: 52

34820 Beykoz / İSTANBUL

Tel: 0 (216) 320 45 50 (Pbx)

Fax: 0 (216) 320 41 45

## 8. MARKETING AUTHORISATION NUMBER

191/57

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31.05.1999

Date of latest renewal: 26.04.2005

## 10. DATE OF REVISION OF THE TEXT

---