

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 metabisulfite 2 mg, methyl paraben 3 mg, propyl paraben 0.4 mg and q.s. water for injection.

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:

- 1. What DEKSAMET is and what it is used for?*
- 2. What you need to know before you use DEKSAMET*
- 3. How to use DEKSAMET?*
- 4. What are the possible side effects?*
- 5. How to store DEKSAMET*

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.

DEKSAMET 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 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 into a vein or muscle by your doctor.

• 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.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

Marketing Authorization Holder and Manufacturer:

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