PACKAGE LEAFLET: INFORMATION FOR THE USER

Dexamethasone Kern Pharma 4 mg/ml solution for injection, Generic medicinal product
Dexamethasone

Read all of this leaflet carefully before you start taking this medicine.
- 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. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT DEXAMETHASONE KERN PHARMA IS AND WHAT IT IS USED FOR

Dexamethasone is an adrenocortical hormone (glucocorticoid) with very high anti-inflammatory and immunosuppressant activity and reduced mineralocorticoid activity.

Its intramuscular or intravenous administration is indicated in the treatment of:
- Acute and chronic inflammatory processes of different origins and in different locations.
- Endocrine diseases.
- Hypercalcaemia associated with cancer and congenital adrenal hyperplasia.
- Severe allergic conditions.
- Both acute and chronic severe inflammatory and allergic processes affecting the eyes.
- Systemic treatment in critical periods of ulcerative colitis and regional enteritis.
- Dermatological diseases, respiratory diseases and haematological diseases.
- Idiopathic nephrotic syndrome (without uraemia) or that caused by lupus erythematosus (autoimmune disease).
- Cerebral oedema associated with brain tumour, craniotomy or cranial lesion.

It is also indicated as:
- Short-term coadjuvant treatment during acute episodes or exacerbations of rheumatic diseases.
- During an exacerbation or as maintenance therapy, in some cases of systemic lupus erythematosus and acute rheumatic carditis.
- For the palliative treatment of leukaemia and lymphomas in adults and acute leukaemia in children.

By the intraarticular or intralesional route or injection in soft tissues, it is indicated:
- As combined short-term therapy in acute episodes or exacerbations of rheumatic diseases.
- By intralesional injection in inflammatory processes.
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2. BEFORE YOU USE DEXAMETHASONE KERN PHARMA

Do not use Dexamethasone Kern Pharma

- If you are allergic to or have had an allergic reaction to the active substance in this medicinal product or any of its ingredients or any other medicinal product. These reactions are more common in patients with a history of allergy to a medicinal product.
- If you have a fungal infection, tuberculosis or parasitic infection, herpes, measles and chickenpox, unless you receive appropriate chemotherapy and are subject to close medical monitoring.
- In prolonged treatments, if you have congestive heart disease, severe myasthenia gravis (muscle weakness), peptic ulcer or oesophagitis (inflammation of the oesophagus), diabetes and ocular herpes simplex.
- If you have to be vaccinated.

Take special care with Dexamethasone Kern Pharma
- If you have inflammatory gastrointestinal diseases, kidney failure, hypertension, osteoporosis or myasthenia gravis (muscle weakness).
- Fatty embolism (accumulation of fat) can present with high doses.
- Exposure to varicella or measles virus should be avoided.
- Due to the risk of adrenal suppression, delayed growth during prolonged treatment in children.
- As cases of osteoporosis can occur, fluid retention and increased blood pressure during treatment in the elderly.
- The joint administration of antibiotics and corticosteroids must be controlled, as the infection could spread if the causal germ is not sensitive to the antibiotic used.
- In treatment with corticosteroids, the lowest possible dose should always be used until the pathological situation is controlled.
- In patients with hypothyroidism or patients with cirrhosis, corticosteroids present an increased pharmacological effect.
- The intraarticular use of a corticosteroid administered by injection can cause systemic and local effects.
- Injection of a corticosteroid in an infected site should be avoided. It should also not be injected in unstable joints. Frequent intraarticular injections can damage joint tissues.

Taking other medicines
Tell your doctor or pharmacist if you are using or have recently used other medicines, including medicines obtained without a prescription, homeopathic medicines, medicinal plants and other health-related products, as it may be necessary to stop the treatment or adjust some of the doses. Remember that these instructions could also be applicable to medicinal products that have been used before or may be used afterwards.

This is particularly important if you are taking the following medicines:

- Epilepsy drugs (phenobarbital and carbamazepine), arrhythmia drugs (phenytoin), asthma drugs and bronchodilators (adrenaline and ephedrine), anti-tuberculosis antibiotics (rifampicin) and cancer drugs (aminoglutethimide) can reduce the therapeutic effect of dexamethasone.
- Oestrogens can increase the effect of dexamethasone.
- Reduced therapeutic effect of salicylates and anthelmintic agents (albendazole).
- It can reduce the effects of antidiabetic agents.
- With medicines used to treat heart diseases (cardiotonic glycosides and potassium-sparing diuretics), it can reduce potassium levels and increase cardiac toxicity.
- There is mutual boosting of toxicity with prostaglandin synthesis inhibitors (indometacin).

- Reduction of plasma levels of some tuberculosis drugs (isoniazid).
- Acetylsalicylic acid should be used with precaution during treatment with dexamethasone.
- Anticoagulants (coumarin and indandione derivatives).

Pregnancy and breast-feeding
Pregnancy
Ask your doctor or pharmacist for advice before taking any medicine.
The use of Dexamethasone Kern Pharma during pregnancy is not recommended. However, your doctor will evaluate the risk/benefit of its use.

Breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Breastfeeding is not recommended for mothers treated with dexamethasone, as this medicine is excreted in breast milk.

Driving and using machines
The effect of Dexamethasone Kern Pharma on driving or using machinery is unknown. Therefore, try not to perform tasks requiring special attention until you check how you tolerate the medicine.

Important information about some of the ingredients in Dexamethasone Kern Pharma
This medicine contains less than 23 mg of sodium per dose; it is therefore essentially "sodium-free".
As it contains propyl parahydroxybenzoate and methyl parahydroxybenzoate, it can cause allergic reactions (possibly delayed) and, rarely, bronchospasm (sudden shortness of breath).

Effect on laboratory results:
This medicine can alter the values of some laboratory tests:
- Blood: increased cholesterol and glucose and reduced calcium, potassium and thyroid hormones.
- Urine: increased glucose.
- Skin tests: tuberculin and patch allergy tests.

If you are asked to undergo a laboratory test, tell your doctor that you are using Dexamethasone Kern Pharma.

Use in athletes:
This medicine contains an ingredient that can produce positive results in doping tests.

3. HOW TO USE DEXAMETHASONE KERN PHARMA

Closely follow your doctor's instructions on how to use Dexamethasone Kern Pharma. If in doubt, ask your doctor or pharmacist.
Dexamethasone Kern Pharma is usually administered by a doctor or nurse.
Dexamethasone Kern Pharma contains 4 mg of dexamethasone per ampoule, for intravenous, intramuscular, intraarticular or intralesional administration or by injection in soft tissues. It can be applied directly or added to a physiological saline or dextrose and administered through a drip.
The dose should be adjusted in patients with kidney and liver failure.

DOSING REQUIREMENTS ARE VARIABLE AND SHOULD BE INDIVIDUALISED BASED ON THE DISEASE AND PATIENT RESPONSE

Intravenous and intramuscular route

As with other steroids, provided the condition allows it, the most appropriate dosage of Dexamethasone Kern Pharma is:

a) Single daily dose in the morning.

b) Single dose on alternate days.

The initial dose of Dexamethasone Kern Pharma ranges from 0.5 to 9 mg per day, depending on the disease being treated. Doses of less than 0.5 mg may be sufficient in less severe processes, while severe diseases may require more than 9 mg. The initial dose should be maintained or adjusted until patient response is satisfactory and, if no suitable clinical response is obtained after a reasonable period of time, it should be discontinued and the patient's treatment changed.

Use in children:

In children, the recommended daily dose is 0.08-0.3 mg/kg or 2.5-10 mg/m².

Intraarticular or intralesional route and injection in soft tissues
This method of administration is used when the affected joints or areas are limited to one or two sites. Dosage and frequency of administration vary, depending on status and administration site; the usual dose is 0.2 to 6 mg and the frequency from once every 3-5 days to once every 2-3 weeks. The repeated administration of intraarticular injections may give rise to joint tissue damage.

Tell your doctor or pharmacist if you believe that the effect of Dexamethasone Kern Pharma is too strong or weak.

If you use more Dexamethasone Kern Pharma than you should
Tell your doctor or pharmacist immediately, or call the Toxicology Information Service. Telephone: 91 562 04 20.

Acute intoxication or death from overdose may occur in a very low percentage of patients. The symptoms that may develop are anxiety, depression, mental confusion, digestive spasms or haemorrhage, hyperglycaemia, hypertension and oedema. In these cases, the administration of phenobarbital is indicated, as well as symptomatic and support treatment including oxygen therapy, maintenance of body temperature, adequate fluid intake and control of electrolytes in serum and urine. Digestive haemorrhage symptoms should be treated in the same way as a peptic ulcer.

If you stop using Dexamethasone Kern Pharma
Your doctor will tell you how long to use Dexamethasone Kern Pharma. Do not suspend the treatment earlier, as your condition would get worse again.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dexamethasone Kern Pharma can cause side effects, although not everybody gets them.

Below is a list of undesirable effects. They have been classified using the following frequency definitions: very common (at least 1 out of every 10 patients), common (at least 1 out of every 100 patients), uncommon (at least 1 out of every 1,000 patients), rare (at least 1 out of every 10,000 patients) and very rare (less than 1 out of every 10,000 patients).

The following undesirable effects have been reported with dexamethasone:

Common:
- Immune system disorders: reduction in resistance to infections, oropharyngeal candidiasis.
- Endocrine disorders: hyperglycaemia, adrenocortical insufficiency.
- At high doses: signs of adrenal hyperactivity (Cushing's syndrome) with rash.
- Metabolism and nutrition disorders: polyphagia (increased appetite).
- Eye disorders: cataracts.
- Vascular disorders: at high doses, hot flashes.
- Gastrointestinal disorders: at high doses: gastric ulcer.
- Skin and subcutaneous tissue disorders: delayed wound healing, allergic skin reaction.
- At high doses: hirsutism (excessive growth of body hair), hyperpigmentation of the skin (darkening of the skin), scleroderma (subcutaneous tissue disorder).
- Musculoskeletal and connective tissue disorders: osteoporosis, brittle bones.
- With prolonged treatments: muscular atrophy.

Uncommon:
- Blood and lymphatic system disorders: lymphopenia, eosinopenia.
- Immune system disorders: generalised allergic reaction.
- Endocrine disorders: amenorrhoea (lack of menstruation). With long-term administration, requiring medical care: Cushing's syndrome, endocrine imbalance.
- Metabolism and nutrition disorders: hypokalaemia (reduction in plasma concentration of potassium), acute pancreatitis, pancreatitis.
- Nervous system disorders: intracranial hypertension, neurological disorders, psychotic states.
- Cardiac disorders: heart failure.
- Vascular disorders: thromboembolism, oedema, hypertension. With long-term administration, requiring medical care: avascular necrosis, oedema.
- Skin and subcutaneous tissue disorders: perspiration. With long-term administration, requiring medical care: acne or other skin problems, scars at the injection site.
- Musculoskeletal and connective tissue disorders: myasthenia (muscle weakness). With long-term administration, requiring medical care: steroidal myopathy (muscle weakness), striae, tendon rupture, osteoporosis or bone fractures.
- General disorders and administration site conditions: With the rapid intravenous administration of high doses: allergic reactions and local infection at the injection site, generalised anaphylaxis, reddening of face or cheeks, irregular heart beat or palpitations, seizures. With local injection: unusual bruising, wounds that do not heal.
- Gastrointestinal disorders: With long-term administration, requiring medical care: gastrointestinal irritation, peptic ulcer or intestinal perforation.

If adverse reactions appear, stop the treatment and seek medical advice.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DEXAMETHASONE KERN PHARMA

Keep out of the reach and sight of children.

Do not freeze. Store in original container to protect from light.

Do not use Dexamethasone Kern Pharma after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION FOR HEALTHCARE PERSONNEL

Only use transparent solutions that are free from turbidity and precipitates.
Other presentations: Clinical box with 100 ampoules.

Composition

- The active substance is dexamethasone. Each ampoule contains: 4 mg of dexamethasone phosphate (as dexamethasone sodium phosphate, 4.37 mg).
- The other ingredients (excipients) are: methyl parahydroxybenzoate (E-218), propyl parahydroxybenzoate (E-216), disodium edetate, sodium citrate (E-331i), sodium hydroxide (E-524) and water for injection.

Appearance of the product and contents of the container

Dexamethasone Kern Pharma is a transparent solution for injection presented in containers with three 1-ml ampoules.

Marketing authorisation holder and manufacturer

KERN PHARMA, S.L.
Polígono Ind. Colón II
Venus, 72
08228 Terrassa (Barcelona) – Spain

This leaflet was last revised in December 2010.