

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Dexamethasone ampoule.

2. Qualitative and quantitative composition

Each ampoule contains:

Dexamethasone sodium phosphate (as disodium salt) 4 mg/ml

For excipients see section 6.

3. Pharmaceutical form

Clear colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

- Dexamethasone Sodium Phosphate has been used in the treatment of conditions for which corticosteroid therapy is indicated for parenteral administration in intensive therapy or in emergencies. Its lack of mineralocortical properties makes Dexamethasone Sodium Phosphate particularly suitable for treating conditions where water retention would be a disadvantage.

By intravenous or intramuscular injection Dexamethasone Sodium Phosphate is used in:

- Anaphylactic shock.
- Status asthmaticus or bronchial asthma.
- Drug hypersensitivity reactions.
- Acute or severe dermatoses.
- Congenital adrenal hyperplasia.
- Acute adrenocortical insufficiency.
- Rheumatoid disorders such as rheumatoid arthritis, acute rheumatic carditis, and acute gouty arthritis.
- Nausea and vomiting induced by cancer chemotherapy.
- Cerebral oedema associated with brain tumour, craniotomy, or head injury.

By intra-articular or soft tissue injection, Dexamethasone Sodium Phosphate has been used in:

- Synovitis of osteoarthritis.
- Rheumatoid arthritis.
- Epicondylitis.
- Acute and subacute bursitis.

4.2 Posology and method of administration

- Dosage must be individualized according to the severity of the disease and the response of the patient. Patients should be closely observed for signs that might require dosage adjustment.
- Allergic reactions, inflammatory conditions, and neoplasias:
Adults: 4 mg I.M. as a single dose. Continue maintenance therapy with dexamethasone tablets.
- Shock:
Adults: 1 – 6 mg/kg body weight as a single dose; or 40 mg I.V. every 2 – 6 hours as needed; or 20 mg I.V. as a single dose followed by continuous infusion of 3 mg/kg per day.
- Cerebral oedema:
Adults: Initially, 10 mg I.V., then 4 mg I.M. every 6 hours until symptoms subside (usually 2 – 4 days); then tapered over 5 – 7 days.
- Dexamethasone Sodium Phosphate injections should be given slowly or by infusion, since rapid intravenous injection of massive doses may sometimes cause cardiovascular collapse.
- After high-dose or prolonged therapy, withdrawal should be gradual, based on patient's response, dose, disease being treated, and duration of therapy.

4.3 Contraindications

- Hypersensitivity to the drug.
- Patients with systemic fungal infections.
- Patients with acute infections uncontrolled by appropriate antimicrobial chemotherapy.
- Dexamethasone Sodium Phosphate should not be administered prior to or immediately after prophylactic vaccination.
- Lactation.

4.4 Special warnings and precautions for use

- Corticosteroids, including Dexamethasone Sodium Phosphate, should only be used systemically with great caution in:
 - Pregnancy.
 - Heart failure, recent myocardial infarction, or hypertension.
 - Patients with diabetes mellitus, osteoporosis, renal disease, hypothyroidism, cirrhosis, diverticulitis, nonspecific ulcerative colitis, recent intestinal anastomoses, seizures, myasthenia gravis, tuberculosis, ocular herpes simplex, emotional instability, or psychotic tendencies.
 - The elderly or children may be at increased risk of side effects.

- During prolonged course of corticosteroids therapy, patients should be examined regularly. Sodium intake may need to be reduced and calcium and potassium supplements may be necessary.
- Following long – term therapy, withdrawal of corticosteroids, including Dexamethasone Sodium Phosphate, may result in symptoms of the corticosteroid withdrawal syndrome including fever, myalgia, arthralgia, and malaise.

4.5 Interaction with other medicinal products

- Antidiabetics, including insulin, result in decreased hypoglycaemic activity.
- Aspirin, indomethacin, or other NSAIDs, increase risk of gastrointestinal distress.
- Barbiturates, phenytoin, rifampin, decrease corticosteroid effect.
- Cardiac glycosides, increase possibility of arrhythmia from hypokalaemia.
- Anticoagulants result in decreased anticoagulant activity.
- Coadministration with potassium depleting diuretics, such as thiazides or furosemide, may cause excessive potassium loss.

4.6 Pregnancy and lactation

Corticosteroids, including Dexamethasone Sodium Phosphate, should only be used systemically with great caution in pregnancy.

Dexamethasone Sodium Phosphate is contraindicated during lactation.

4.7 Effects on ability to drive and use machines

None Known.

4.8 Undesirable effects

- Dexamethasone Sodium Phosphate injection is generally administered systemically for short- term therapy and in acute conditions. Therefore, the risk of side effects is low. However, continued medical supervision of the patient during therapy and after cessation of the drug is essential.

- The side effects may include euphoria, insomnia, seizures, psychotic behaviour, hypertension, oedema, arrhythmias, peptic ulceration, gastrointestinal irritation, increased appetite, pancreatitis, hypokalaemia, hyperglycaemia, muscle weakness, osteoporosis, delayed wound healing, atrophy at intramuscular sites, and susceptibility to infections.

Long- term therapy in children and adolescents may delay growth and maturation.

4.9 Overdose

None Known.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Dexamethasone Sodium Phosphate is a synthetic adrenocortical steroid with glucocorticoid activity. It has a rapid onset but short duration of action when compared with less soluble preparations. Consequently, it is suitable for the treatment of acute disorders responsive to adrenocortical steroid therapy. It is primarily used for its potent anti-inflammatory effects in disorders of many organ systems.

5.2 Pharmacokinetic properties

Corticosteroids, including Dexamethasone Sodium Phosphate, may be given by intravenous injection for a rapid response; more prolonged effects are achieved by intramuscular injection. They are rapidly distributed to all body tissues. Dexamethasone Sodium Phosphate, and other synthetic corticosteroids, are bound weakly to plasma proteins. Only unbound portion is active. The drug is metabolized in the liver to inactive metabolites; the unchanged drug and the metabolites are primarily excreted in urine and insignificant amounts are excreted in faeces. The elimination half-life is about 36 to 54 hours. The slower metabolism of the synthetic corticosteroids, including Dexamethasone Sodium Phosphate, with their lower protein-binding affinity may account for their increased potency compared with natural corticosteroids.

6. Pharmaceutical particulars

6.1 List of excipients

Creatinine, sodium citrate, sodium metabisulphite, sodium hydroxide, methyl paraben, propyl paraben, water for injection.

6.2 Incompatibilities

None known.

6.3 Special precautions for storage

Store at temp. not exceeding 20°C.

6.4 Nature and contents of container

Dexamethasone Sodium Phosphate 1 ml, 2ml Ampoules: Boxes of 5 or 100 ampoules, each.

6.5 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

EIPICO

8. Marketing authorization number

06578/07603/REN/2020

9. Date of revision of the text

June 2010.