Odeson® IM/IV Injection

Dexamethasone Phosphate

Description

Dexamethasone sodium phosphate is a type of medicine known as a corticosteroid. Corticosteroids are hormones produced naturally by the adrenal glands which have many important functions on every organ system.

Indications

Endocrine disorders

Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance).

Acute adrenocortical insufficiency, pre-operatively and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful. Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected

congenital adrenal hyperplasia, nonsuppurative thyroiditis, hypercalcemia associated with cancer

Rheumatic disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: post-traumatic osteoarthritis, synovitis of osteoarthritis, rheumatoid arthritis including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), acute and sub-acute bursitis, epicondylitis, acute nonspecific tenosynovitis, acute gouty arthritis, psoriatic arthritis, ankylosing spondylitis.

Collagen diseases

During an exacerbation or as maintenance therapy in selected cases of Systemic lupus erythematosus and acute rheumatic carditis

Dermatologic diseases

Pemphigus,Severe erythema multiforme (Stevens-Johnson syndrome), Exfoliative dermatitis,Bullous dermatitis herpetiformis, Severe seborrheic dermatitis,Severe psoriasis, Mycosis fungoides

Allergic states

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in bronchial asthma, contact dermatitis, atopic dermatitis, serum sickness, seasonal or perennial allergic rhinitis, drug hypersensitivity reactions, urticarial transfusion reactions, acute non-infectious laryngeal edema (epinephrine is the drug of first choice)

Ophthalmic diseases

Severe acute and chronic allergic and inflammatory processes involving the eye, such as: herpes zoster ophthalmicus, iritis, iridocyclitis, chorioretinitis, diffuse posterior uveitis and choroiditis, optic neuritis, sympathetic ophthalmia, anterior segment inflammation, allergic conjunctivitis, keratitis, allergic corneal marginal ulcers.

Gastrointestinal diseases

To tide the patient over a critical period of the disease in ulcerative colitis (systemic therapy), regional enteritis (systemic therapy)

Respiratory diseases

Symptomatic sarcoidosis, berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy, Loeffler's syndrome not manageable by other means, aspiration pneumonitis.

Hematologic disorders

Acquired (autoimmune) hemolytic anemia, idiopathic thrombocytopenic purpura in adults (I.V. only: I.M administration is contraindicated), secondary thrombocytopenia in adults, erythroblastopenia (RBC anemia), congenital (erythroid) hypoplasticanemia

Neoplastic diseases

For palliative management of leukemias and lymphomas in adults, acute leukemia of childhood.

Edematous states

To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.

Miscellaneous

Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy,Trichinosis with neurologic or myocardial involvement

Cerebral Edema

Cerebral Edema associated with primary or metastatic brain tumor, craniotomy, or head injury. Use in cerebral edema is not a substitute for careful neurosurgical evaluation and definitive management such as neurosurgery or other specific therapy.

May also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

Dosage and Administration

In general, glucocorticoid dosage depends on the severity of the condition and response of the patient. Under certain circumstances, for instance in stress, extra dosage adjustments may be necessary. If no favourable response is noted within a couple of days, glucocorticoid therapy should be discontinued.

Adults and Elderly

Once the disease is under control the dosage should be reduced or tapered off to the lowest suitable level under continuous monitoring and observation of the patient.

For acute life-threatening situations (e.g. anaphylaxis, acute severe asthma) substantially higher dosages may be needed. Cerebral oedema (adults): initial dose 8-16 mg IV followed by 5 mg IV or IM every 6 hours, until a satisfactory result has been obtained. In brain surgery these dosages may be necessary until several days after the operation. Thereafter, the dosage has to be tapered off gradually. Increase of intracranial pressure associated with brain tumours can be counteracted by continuous treatment.

For local treatment, the following dosages can be recommended:

intra-articulary:	1.6-3 mg large joints 0.6-0.8 mg small joints
intrabursally:	1.6-3 mg;
in tendon sheaths:	0.3-0.8 mg

The frequency of these injections may vary from every 3-5 days to every 2 -3 weeks.

For rectal drip in cases of ulcerative colitis: 4 mg diluted in 120 ml saline.

Suggested doses for children

Dosage requirements are variable and may have to be changed according to individual needs. Usually 0.2 mg/kg to 0.4 mg/kg of body weight daily.

Administration

Dexamethasone injections may be administered intravenously, subcutaneously, intramuscularly, by local injection or as a rectal drip.

148 x 210mm

For administration by intravenous infusion: see section on compatibility with infusion fluids. With intravenous administration high plasma levels can be obtained rapidly.

Rapid intravenous injection of massive doses of glucocorticoids may sometimes cause cardiovascular collapse; the injection should therefore be given slowly over a period of several minutes.

Intra-articular injections should be given under strictly aseptic conditions.

Side Effects

Medicines and their possible side effects can affect individual people in different ways. The following are some of the side effects that are known to be associated with this medicine. Because a side effect is stated here, it does not mean that all people using this medicine will experience that or any side effect.

Difficulty in sleeping (insomnia), depression, weight gain, irregular menstrual cycle, decreased functioning of the adrenal, gland (adrenal suppression), thinning of the bones (osteoporosis), ulceration of the stomach or intestine, increased susceptibility to infections, acne, extreme allergic reaction (anaphylaxis), increased risk of fractures of the bones, breathing difficulties due to a narrowing of the airways (bronchospasm), increased hair growth (hirsutism), yeast infection of the moist areas of the body, especially the vagina (candidiasis), supression of growth in children and adolescents, muscle wasting and weakness.

Contraindications

- Infection of the joint or surrounding tissue (joint injection only)
- Infection throughout the body (systemic infection) unless treated with specific anti-infectives
- Protozoal infection of the intestine (amoebiasis)
- Unstable joints

This medicine should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such an allergy.

Warning

- Avoid close personal contact with people who have chickenpox or shingles (herpes zoster).
- Do not stop taking this medicine suddenly, particularly if you have been taking it for longer than 3 weeks. This is because long-term use of the medicine suppresses the natural production of corticosteroids by the adrenal glands. This means that the body becomes temporarily reliant on the medicine. When it is time to stop treatment the dose should be tapered down gradually, to allow the adrenal glands to start producing adequate amounts of natural steroids again.
- This medicine may increase susceptibility to infections and also mask the symptoms of these infections.
- Following joint injection, the occurrence of a distinct increase in pain accompanied by swelling, further restriction of joint movement, fever and malaise are suggestive of an infected arthritis. Antimicrobial treatment should be given to treat this complication.
- Injections administered into joints are associated with a risk of infection. Any fluid present in the joint should be examined to exclude bacterial infection before starting treatment. These injections should only be given under sterile conditions.
- Tests should be performed to exclude protozoal infection of the intestine (amoebiasis) and roundworm infection (strongyloidiasis) before starting treatment.
- It is important not to overuse joints in which a benefit has been obtained by joint injection, as the inflammatory process may remain active.

Precaution

Withdrawal syndrome including fever, myalgia, arthralgia and malaise. This may occur in patients even without evidence of adrenal insufficiency. Emotional instability or psychotic tendencies may be aggravated by corticosteroids.

High Risk Group

Pregnancy and Breastfeeding

- The drug should be used with caution during pregnancy only if the expected benefit to the mother is greater than any possible risk to the foetus.
- The safety of this medicine during breastfeeding has not been established.

Drug Interactions

The following medicines may increase the removal of corticosteroids from the body, thus reducing their effects:

- antiepileptics: carbamazepine and phenytoin
- barbituates: phenobarbitone
- rifampicin
- aminoglutethimide

When taken with carbenoxolone, amphotericin or diuretics e.g. frusemide, there is an increased risk of low blood potassium levels (hypokalaemia).

When taken with non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indomethacin, there is an increased risk of adverse effects on the gut, such as stomach ulceration and bleeding.

The blood levels of salicylates e.g. aspirin, are decreased by corticosteroids and therefore may increase to excessive levels once the corticosteroid is stopped.

Corticosteroids may oppose the treatment of high blood pressure and heart failure as they may cause retention of salt and water.

As corticosteroids may increase blood sugar, they can oppose the blood sugar lowering effects of antidiabetic medicines.

Live vaccines should not be administered to people taking corticosteroids, as their normal immune response is reduced and giving a live vaccine may therefore result in infection rather than the production of antibodies.

Commercial Pack

Odeson IM/IV Injection: Box contains 2x5 ampoules of 1 ml sterile injection in blister pack. Each 1 ml contains Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone Phosphate 4 mg.

BEXIMCO PHARMA

Manufactured by

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148 x 210mm