Glucort Injection

Hydrocortisone sodium succinate

Presentation:

Glucort IM/IV Injection: Each vial contains sterile powder of Hydrocortisone sodium succinate USP, equivalent to 100 mg Hydrocortisone

Description

Hydrocortisone, a naturally occurring glucocorticoid, which has also salt- retaining properties, is used as replacement therapy in adrenocortical deficiency states. This synthetic analog is primarily used for their anti-inflammatory effects in disorders of many organ systems by inhibiting the synthesis of phospholipase A2. Hydrocortisone reduces various vasoactive agents released during inflammation.

Hydrocortisone sodium succinate has the same metabolic and anti-inflammatory actions as hydrocortisone. The highly water-soluble sodium succinate ester of hydrocortisone permits the immediate intravenous administration of high doses of hydrocortisone in a small volume of diluent and is particularly useful where high blood levels of hydrocortisone are required rapidly. This preparation is also rapidly absorbed when administered intramuscularly.

Indications

Hydrocortisone sodium succinate for injection is indicated for IM or IV use in the following conditions:

- ***Endocrine disorder***
  Primary or secondary adrenocortical insufficiency, Acute adrenocortical insufficiency, Shock unresponsive to conventional, Congenital adrenal hyperplasia, Nonsuppurative thyroiditis. Hypercalcemia associated with cancer.
- ***Rheumatic disorder***
  Rheumatoid arthritis, including juvenile rheumatoid arthritis acute and subacute bursitis; epicondylitis; acute nonspecific tenosynovitis ; acute gouty arthritis; psoriatic arthritis; ankylosing spondylitis.
- ***Collagen disease***
  During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus; acute rheumatic carditis; systemic dermatomyositis (polymyositis).
- ***Dermatological disease***
  Pemphigus; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; bullous dermatitis herpetiformis; severe seborrheic dermatitis; severe psoriasis; mucosis fungoides.
- ***Allergic states***
  Controls bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness; seasonal or perennial allergic rhinitis; drug hypersensitivity reaction; urticarial transfusion reactions; acute noninfectious laryngeal edema (epinephrine is the drug of first choice); anaphylactic reactions.
- ***Ophthalmic disease***
  Severe acute and chronic allergic and inflammatory processes involving the eye, such as: herpes zoster ophthalmicus; iritis, iridocyclitis; chorioretinitis; diffuse posterior uveitis and chroiditis; optic neuritis; sympathetic ophthalmia; anterior segment inflammation; allergic conjunctivitis; allergic corneal marginal ulcers; keratitis.
- ***Gastrointestinal disease***
  To tide the patient over a critical period of the disease in: ulcerative colitis (systemic therapy); regional enteritis (systemic therapy); Crohn's disease.
- ***Respiratory disease***
  Symptomatic sarcoidosis; berylliosis; fulminating or disseminate pulmonary tuberculosis when used concurrently with appropriate antituberculosis chemotherapy; Loeffler syndrome not manageable by other means; aspiration pneumonitis.
- ***Hematologic disorder***
  Acquired (autoimmune) hemolytic anemia; idiopathic thrombocytopenia purpura in adults (IV only; IM administration is contraindicated); erythroblastopenia (RBC anemia); congenital (erythroid) hypoplastic anemia; secondary thrombocytopenia in adults.
- ***Neoplastic disease***
  For palliative management of: leukemias and lymphoma in adults; acute leukemia of childhood.
- ***Edematous state***
  To induce diuresis or remission of proteinuria in the nephritic 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 antituberculosis chemotherapy. Trichinosis with neurologic or myocardial involvement.

Dosage & Administration

Hydrocortisone sodium succinate for injection may be administered by intravenous injection , by intramuscular injection or by intravenous infusion injection, the preferred method for initial emergency use being intravenous injection. Following the initial emergency period consideration should be given to employ a longer-acting injectable preparation or an oral preparation.

Adult: Dosages usually range from 100 mg to 500 mg depending on severity of the condition, administered by intravenous injection over a period of one to ten minutes. This dose may be repeated at intervals of 2, 4 or 6 hours as indicated by the patient's response and clinical condition.
It should be noted that dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient.

In pediatric patients: The initial dose of Hydrocortisone may vary depending on the specific disease entity being treated. The range of initial dose is 0.56 to 8 mg/kg/day in 3 to 4 divided doses.

Preparation for Solutions

For intravenous or intramuscular injection prepare the solution aseptically by adding not more than 2 ml sterile water for injections to the vial containing 100 mg. Shake and withdraw for use.
For intravenous infusion, prepare a primary solution as above and than add 100 -1000 ml (not less than 100 ml) of 5% dextrose in water, or isotonic saline or 5% dextrose in isotonic saline solution, if patient is not on sodium restriction.
When reconstituted as directed, the pH of the solution will range from 7.0 - 8.0.

Contraindication

Hydrocortisone sodium succinate for injection is contraindicated where there is known hypersensitivity to components and in systemic fungal infection unless specific anti- infective therapy is employed. Administration of live or live-attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids.

Side Effect

Possible side effects may include: headaches, vomiting, dizziness, mood swings, acne, facial redness, menstrual irregularities. The following side effects are more serious and require immediate medical attention: Abnormal weakness, muscle pains, joint pains, Vision changes or problems, Any symptoms of an allergic reaction, such as swelling, skin rashes, hives, trouble breathing, and trouble swallowing

Precaution

Use Hydrocortisone sodium succinate cautiously in patients with a recent MI, GI ulcer, renal disease, hypertension, osteoporosis, diabetes mellitus, hypothyroidism, cirrhosis, diverticulitis, ulcerative colitis, recent intestinal anastomosis, thromboembolic disorders, seizures, myasthenia gravis, heart failure, tuberculosis, ocular herpes simplex, emotional instability, and psychotic tendencies.

Use in Pregnancy & Lactation

Many corticosteroids have been shown to be teratogenic in laboratory animals at low doses. Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers, or women of child bearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and the embryo, fetus or nursing infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Overdose

Treatment of acute over dosage is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

Drug Interaction

Coadministration of corticosteroids and Warfarin usually results in inhibition of response to Warferin. Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance. With antidiabetics, corticosteroids may increase blood glucose concentration, dosage adjustment of antidiabetic agents may be required. Drugs that induce hepatic enzymes such as Phenobarbital, Phenytoin and Carbamezepine may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response. Drugs such as Troleandomycin and Ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore, the dose of corticosteroid should be titrated to avoid steroid toxicity.

Storage

Glucort injection should be kept in a cool (below 30° C) and dry place and protected from light. Use solution only if it is clear.

Commercial Pack

Glucort IM/IV Injection: Each vial contains sterile powder of Hydrocortisone sodium succinate USP equivalent to Hydrocortisone 100 mg and one ampoule of 2 ml water for injection BP.

Manufactured by:

Globe Pharmaceuticals Ltd.
Noakhali, Bangladesh