Hydrocortisone Sodium Succinate

Costeron-H®

100mg Powder for Injection
(IM /IV)

CORTICOSTEROID

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DESCRIPTION
Each vial contains hydrocortisone sodium succinate equivalent to 100 mg of hydrocortisone.

FORMULATION
Each vial contains Hydrocortisone (as sodium succinate) 100mg

PHARMACOLOGY: Pharmacodynamics: Mechanism of Action: It is an adrenocortical steroid influencing the carbohydrate, protein and lipid metabolism, electrolyte and water balance, functioning of cardiovascular system, kidney, skeletal muscles and nervous system. Acts by inhibiting release of adrenocorticotropic hormone (ACTH) thereby, controlling the rate of protein synthesis. It stimulates formation of glucose, lessens its peripheral utilization and promotes storage as glycogen. It influences lipid metabolism by re-distribution of body fats, eliciting lipolysis of the triglycerides of adipose tissue, possesses salt-retaining property thereby, influencing electrolyte-water balance.
PHARMACOKINETICS: Hydrocortisone is readily absorbed in the gastrointestinal tract and peak blood concentrations are attained in about an hour. The biological half-life (t½) is about 100 min. It is >90% bound to plasma proteins. Following IM injection, the absorption of the water-soluble sodium phosphate and sodium succinate esters is rapid, while the absorption of free alcohol and its lipid soluble esters is usually slower. Absorption of hydrocortisone acetate after intra-articular or soft tissue injection is also slow. Hydrocortisone is absorbed through the skin particularly on denuded areas.
Hydrocortisone is metabolized in the liver and most body tissues to hydrogenated and degraded forms eg, tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucoronides together with a very small proportion of unchanged hydrocortisone. Hydrocortisone readily crosses the placenta.

INDICATIONS
Used in the management of all conditions in which corticosteroids are indicated. Also for replacement therapy in acute or chronic adrenocortical insufficiency.

CONTRA-INDICATIONS/PRECAUTIONS
During long course of corticosteroid therapy patients should be examined regularly, and in particular, checked for hypertension, glycosuria, hypokalaemia, gastric discomfort and mental changes. Measures to compensate for the adrenal inability to respond to stress include increasing the dose to cover intercurrent illness or trauma such as surgery (with intramuscular administration to cover vomiting.) Rapid intravenous injection of massive doses of corticosteroids may sometimes cause cardiovascular collapse and injections should therefore, be given slowly or by infusion. High dose should not be used for prolonged treatment.
Concurrent administration of barbiturates, Carbamazepine, phenytoin, primidone, or Rifampicin may enhance the metabolism and reduce the effects of corticosteroids.
Concurrent administration of corticosteroids with potassium depleting diuretics such as thiazides or frusemides, may cause excessive potassium loss. There may be an increase incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with non-steroidal anti-inflammatory drugs. Response to anticoagulants may be altered by corticosteroids and requirements of diabetic agents and antihypertensive may be increased.

DOSAGE & ADMINISTRATION
The usual dose is the equivalent of 100 to 500 mg of hydrocortisone, repeated 3 or 4 times in 24 hours, according to the severity of the condition and the patient's response. Children up to 1 year of age may be given 25mg, 1 to 5 years 50 mg, and 6 to 12 years 100 mg. In the treatment of severe shock the equivalent of up to 50 mg per kg body-weight in 24 hours has been given by slow intravenous injection over several minutes in divided doses, or by intravenous infusion. Fluids and Electrolytes should be given as necessary to correct any associated metabolic disorder. Similar doses to those specified above may also be given intramuscularly but the response is likely to be less rapid than that observed following intravenous administration. Hydrocortisone Sodium Succinate may be given by intravenous injection in a dose equivalent to 100mg to 300mg of Hydrocortisone.
In patients with adrenal insufficiency states supplementary corticosteroid therapy may be necessary during some surgical operations and Hydrocortisone Sodium Succinate may be given intramuscularly or intravenously before surgery.
The equivalent of Hydrocortisone 100 mg may be given with premedication and repeated every 8 hours. For local administration by injection into soft tissues, Hydrocortisone Sodium Succinate is usually given in a dose of 100mg to 200mg or as prescribed by the physician.

PREGNANCY AND LACTATION
Costeron-H is under Pregnancy Category C.
Category C: Either studies in animals have revealed adverse effects on the foetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the foetus

ADVERSE REACTIONS
Acute adrenal insufficiency may occur during prolonged treatment or on cessation of treatment and may be precipitated by stressful situations. For example, infection or trauma. Growth retardation in children has been reported. High doses of corticosteroids administered during pregnancy may cause foetal or neonatal adrenal suppression.
Large doses of corticosteroids, or corticotrophin, may produce Cushing's syndrome, typical of hyperactivity of the adrenal cortex, with moon face, sometimes with hirsutism bufallo hump, flushing, increased bruising, ecchymoses, striae, and acne, sometimes leading to a fully developed Cushing's syndrome. If administration is discontinued, these symptoms are usually reversed, but sudden cessation is dangerous. Rapid intravenous administration of large dose of corticosteroids may cause cardiovascular collapse. Other adverse effects include amenorrhoea, hyperhydrosis, skin thinning, ocular changes including development of cataract, mental and neurological disturbances, intracranial hypertension, acute pancreatitis, and aceptic necrosis of bone. An increase in the coagulability of the blood may lead to thrombo-embolic complications. Muscle weakness and wasting occur occasionally, particularly when corticosteroids are taken in large doses.

REPORTING OF SUSPECTED ADVERSE DRUG REACTION
To show continued monitoring of benefit/risk balance of the medicinal product, reporting suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA:www.fda.gov.ph. Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

STORAGE
Hydrocortisone Sodium Succinate for Injection should be stored at a temperature not exceeding 30°C.

AVAILABILITY
The product is available as dry powder for injection in 6 ml vial.For intramuscular or intravenous injection.

DIRECTIONS FOR RECONSTITUTION
Add 2 mL Sterile Water for injection to make a clear solution. Use immediately after reconstitution. Discard unused mixture.

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CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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