EXICORT® 100

Hydrocortisone (as sodium succinate)

Each vial of Exicort® contains:
Hydrocortisone (as sodium succinate) ..... 100 mg

Description:
Exicort® 100 injection(Hydrocortisone sodium succinate injectable powder) is a synthetic steroid that has anti-inflammatory effect.

Clinical Pharmacology:
Mechanism of Action: Decreases inflammation by suppression of migration of polymorphonuclear leukocytes and reversal of increased capillary permeability. (1)

Pharmacodynamics/kinetics:
Onset of action: Hydrocortisone sodium succinate (water soluble): Rapid
Absorption: Rapid
Metabolism: Hepatic
Half-life elimination: Biologic: 8-12 hours.
Excretion: urine Primarily as 17-hydroxysteroids and 17-ketosteroids) (1)

Indications:
Allergic disorders, Anaphylactic reactions, edema, laryngeal, acute noninfectious, Rhinitis (Allergic, perennial or seasonal) serum sickness, transfusion reactions, urticarial, carditis, rheumatic or nonrheumatic, Dermatomyositis, systemic (polymyositis), lupus erythematosus, Dermatitis types, Granuloma annulare, keloids, Lichen simplex chronicus (neurodermatitis), Lupus erytematosus, discoid, mycosis fungoides, necrobiosis Lipoidica diabeticorum, pernohigus, endocrine disorders, Adrenocortical insufficiency, secondary, congential adrenal hyperplasia, thyroiditis, nonsuppurative, gastrointestinal disorders: (colitis, ulcerative, crohns disease), Hematologic disorders, inflammatory disorders, neurologic disease, neurotrauma, ophthalmic disorders,oral disorders, Rheumatic disorders.(2)

Contraindications:
Hypersensitivity to hydrocortisone or any component of the formulation; serious infections except septic shock or tuberculous meningitis, viral, fungal or tubercular skin lesions, I.M. administration contraindicated in idiopathic thrombocytopenia purpura; intrathecal administration of injection. (1)

Precautions:
Use with caution in patients with thyroid disease, hepatic impairment, renal impairment, heart failure, hypertension, diabetes, glaucoma, cataracts, myasthenia gravis, patients at risk for osteoporosis, patients at risk for seizures or GI disease(diverticulitis, peptic ulcer, ulcerative colitis) due to perforation risk.
Use caution following acute MI (corticosteroids have been associated with myocardial rupture). Corticosteroid use my cause psychiatric disturbances, including depression, euphoria, insomnia, mood swings and personality changes.Pre-existing psychiatric conditions may be exacerbated by corticosteroid use. Prolonged use of corticosteroids may also increase the incidence of secondary infection, mask acute infection (including fungal infections), Prolong or exacerbate viral infections or limit response to vaccines. Prolonged treatment with corticosteroids has been associated with the development of kaposi's sarcoma (case reports); if noted, discontinuation of therapy should be considered. (1)

Pregnancy:
Category C.(1)

Breast feeding:
Enters breast milk/use caution.(1)

Dosage:
Usual adult and adolescent dose:
Corticosteroids:
Intramuscular or intravenous 100 to 500 mg (base): may be repeated every two to six hours, depending upon patient condition and response.
Note: Initial intravenous dosage should be administered over a period of thirty seconds (100 mg dose) to ten minutes (dose 500 mg or higher).
Maintenance dosage (if required) should be no less than 25 mg per day.
Usual pediatric dose:
Adreno cortical insufficiency:
Intramuscular or intravenous 0.19 to 0.28 mg (base) per kg of body weight or 10 to 12 mg per square meter of body surface area a day in three divided doses.
Other indications:
Intramuscular 0.67 to 4 mg per kg of body weight or 20 to 120 mg per square meter of body surface area every twelve to twenty-four hours.(2)

Administration:
Reconstitute the vial by adding not more than 2 ml of sterile water for injection.
Parenteral: Hydrocortisone sodium succinate may be administered by I.M. or I.V. routes.
Dermal or/and subdermal skin depression may occur at the site of injection.
Avoid injection into deltoid muscle (high incidence of subcutaneous atrophy).
I.V. bolus: Dilute to 50mg/ml and Administer over 30 second or over 10 minutes for doses ⩾ 500mg.
I.V. Intermittent Infusion: Dilute to 1mg/ml and Administer over 20-30 minutes .(1)
Dextrose 5%, Sodium chloride 0.9% and dextrose 5% in sodium chloride 0.9% have been recommended as diluents for the administration of hydrocortisone sodium succinate as an intravenous infusion.(3)

Patient consultation:
Before using this medication
Use in Children: Infants born to women who received corticosteroids during pregnancy should be monitored for signs of hypoadrenalism.
Use in the elderly: Dose selection should be caution; especially in postmenopausal femals, aminoglutethimide, omphotericin B, antacids, anticholinesterases, antidiabetic agents.For all uses: Acquired immunodeficiency syndrome (AIDS): Anastomoses, intestinal, recent; cardiac disease; chickenpox; congestive heart failure; diabetes mellitus; esophagitis, gastritis or peptic ulcer; fungal infections; human immunodeficiency virus (HIV) infection, measles; myasthenia gravis; myocardial infarction.
Precaution while using this medication:
Regular visits to physician to check progress during and following therapy.
Checking with physician before discontinuing medication; gradual dosage reduction may be necessary.
Checking with physician if symptoms recur or worsen when dose decreased or therapy discontinued.
For patients on long-term therapy:
- Possible need for sodium restriction or potassium supplementation.
- Possible need for calorie restriction.
- Possible need for increased protein intake.
- Possible need for ophthalmic examinations.
Carrying medical identification card indicating use of corticosteroids.
- Caution in receiving skin test.
- Caution if any kind of surgery or emergency treatment is required.
- Caution if serious infections or injuries occur.
- Avoiding exposure to chickenpox or measles (especially for children): Telling physician right away if exposure occur.
- Caution if receiving vaccinations or other immunizations or coming in contact with persons receiving oral poliovirus vaccine.
- For patients with diabetes: may increase blood glucose concentrations for parenteral dosage forms.
- Restricting use of joint following intra-articular injection.
- Checking with physician if redness or swelling occurs and continues or becomes worse following local injection.(2)

Warning:
May affect growth velocity; growth should be routinely monitored in pediatric patients. withdraw therapy with gradual tapering of dose.
May cause hypercorticism or suppression of hypothalamic-pituitary-adrenal (HPA) axis, particularly in younger children or in Patients receiving high doses for prolonged periods.
HPA axis suppression may lead to adrenal crisis.
Withdrawal and discontinuation of a corticosteroid should be done slowly and carefully.
Acute myopathy has been reported with high dose corticosteroids, usually in patients with neuromuscular transmission disorders; may involve ocular and/or respiratory muscles; monitor creatine kinase; recovery may be delayed.
Exposure to chickenpox should be avoided, corticosteroids should not be used to treat ocular herpes simplex. Corticosteroids should not be used cerebral malaria or viral hepatitis.Oral steroid treatment is not recommended for the treatment of acute optic neuritis.
High-dose corticosteroids should not be used to manage acute head injury. (1)

Interactions:
Aldesleukin, BCG, Natalizumab, Pimecrolimus, Roflumilast, Tacrolimus (topical), Ethanol, Acetylcholinesterase inhibitors, Amphotericin B, Leflunomid, Loop diuretics, NSAIDs, Thiazide Diuretics vaccines (live), Warfarin, Antifungal agents (Fluconazole), Calcium Channel Blockers, Estrongen Derivatives, Neuromuscular-Blocking Agents, Quinolone, Antibiotics, Corticorelin, Aminoglutethimide, Antacids, St john's wort, Cat's claw, Echinacea.
Food: Hydrocortisone interferes with calcium absorption.(1)

Adverse reactions:
Frequency not defined.
Cardiovascular: Arrhythmias, bradycardia, cardiac arrest, cardiomegaly, circulatory collapse, congestive heart failure, edema, fat embolism, hypertension, hypertrophic cardiomyopathy (premature infants), myocardial rapture (post MI),syncope, tachycardia, thromboembolism, vasculitis, Central nervous system: Delirium, depression, emotional instability, euphoria, hallucinations, headache, insomnia, intracranial pressure increased, malaise, mood swings,nervousness, neuritis ,neuropathy, personality changes, pseudotumor cerebri, psychic disorders, psychoses, seizure, vertigo.
Dermatologic: Acne, Allergic dermatitis, Alopesia, bruising, burning/tingling, dry scaly skin, edema, erythema, hirsutism, hyper/hypopigmentation, impaired, wound healing, petechiae, rash, skin atrophy, skin test reaction impaired, sterile, abscess, striae, urticaria.
Endocrine & metabolic: Adrenal suppression, alkalosis, amenorrhea, carbohydrate intolerance increased, cushing's syndrome, diabetes mellitus, glucose intolerance, growth suppression, hyperglycemia, hyperlipidemia, hypokalemia, hypokalemic alkalosis, menstrual irregularities ,negative nitrogen balance, pituitary-adrenal axis suppression, potassium loss, protein catabolism, sodium and water retention, sperm motility increased/decreased, spermatogenesis increased/decreased.
Gastrointestinal: Abdominal distention, appetite increased, bowel dysfunction (intrathecal administration), indigestion, nausea, pancreatitis, peptic ulcerv, gastrointestinal perforation, ulcerative esophagitis, vomiting, weight gain.
Genitourinary: Bladder dysfunction (intrathecal administration).
Hematologic: Leukocytosis (transient).
Hepatic: Hepatomegaly, transaminases increased.
Local: Atrophy(at injection site), postinjection flare(intra-articular use), thrombophebitis.
neuromuscular & skeletal: Arthralgia, necrosis(femoral and humoral heads), charcot-like arthropathy, fractures, muscle mass loss, muscle weakness, myopathy, osteoporosis, tendon tupture, vertebral compression fractures.
Ocular: Cataracts, exophthalmoses, glaucoma, intraocular pressure increased.
Miscellaneous: Abnormal fat deposits, anaphylaxis, avascular, necrosis, diaphoresis, hiccups, hypersensitivity reactions, infection, secondary malignancy.(1)

Over dosage:
In case of overdose contact a physician or poison center.(2)

Storage and Stability Condition:
- Use reconstituted solution only if it is clear.
- Keep out of the reach of children.
- Store below 30°C.
- Protect from light and freezing. (2)

Packaging:
Boxes of one vial.
Boxes of 25 vials.
Boxes of one vial with 1-ml vial of sterile water for injection.

References:
1- Lexicomp's drug reference hand book 20th edition, pages:853-855
2- USPDI 2007, 27th edition, Drug Information for the Health care professional,volume 1 pages 938-957.
3- Hand book on Injectable Drugs 16th edition Trissel volume II, page:870

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