SIZE L 80 x H 150 MM

the morning and the smaller in the early evening, to mimic the circadian rhythm of the body). Children may be given 400 to 800 micrograms/kg daily in 2 or 3 divided doses, adjusted as needed. Additional sodium chloride may be required if there is defective aldosterone secretion, but mineralocorticoid activity is usually supplemented by fludrocortisone acetate orally. Similar regimens have also been used to correct glucocorticoid deficiency in the salt-losing form of congenital adrenal hyperplasia. Hydrocortisone may be given **intravenously**, by slow injection or infusion, in the form of a water-soluble derivative such as hydrocortisone sodium succinate or hydrocortisone sodium phosphate when a rapid effect is required in **emergencies**: such conditions are acute adrenocortical insufficiency caused by Addisonian or post-adrenalectomy crises, by the abrupt accidental withdrawal of therapy in corticosteroid-treated patients, or by the inability of the adrenal glands to cope with increased stress in such patients; certain allergic emergencies such as anaphylaxis; acute severe asthma (status asthmaticus and shock. 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 25 mg, those aged 1 to 5 years 50 mg, and those aged 6 to 12 years 100 mg. 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 after intravenous doses. Corticosteroids are considered to be of secondary value in anaphylactic shock because of their relatively slow onset of action, but intravenous hydrocortisone may be a useful adjunct to adrenaline to prevent further deterioration in severely affected patients. In patients with adrenal deficiency states supplementary corticosteroid therapy may be necessary during some **surgical operations** and hydrocortisone sodium succinate or sodium phosphate may be given intramuscularly or intravenously before surgery. Various regimens have been proposed.

In patients taking more than 10 mg of oral prednisolone or its equivalent daily, the *BNF* recommends the following regimen:

*minor surgery under general anaesthesia*, either the usual oral corticosteroid dose on the morning of surgery *or* hydrocortisone 25 to 50 mg (usually as the sodium succinate) intravenously at induction; the usual oral corticosteroid dose is resumed after surgery

*moderate or major surgery*, the usual oral corticosteroid dose on the morning of surgery, *plus* hydrocortisone 25 to 50 mg intravenously at induction, and followed by similar doses of hydrocortisone 3 times daily, for 24 hours after moderate surgery and 48 to 72 hours after major surgery; the usual corticosteroid dose is resumed once hydrocortisone injections are stopped.

**Pregnancy: Teratogenic effects: Pregnancy Category C.**

Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

**SIDE EFFECT**

Stomach upset, headache, dizziness, trouble sleeping, appetite changes, menstrual period changes, acne, or pain/redness/swelling at the injection site may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

This medication may make your blood sugar rise, which can cause or worsen diabetes. Tell your doctor right away if you have symptoms of high blood sugar such as increased thirst/urination. If you already have diabetes, check your blood sugar regularly as directed and share the results with your doctor. Your doctor may need to adjust your diabetes medication, exercise program, or diet.

This medication may lower your ability to fight infections. This may make you more likely to get a serious (rarely fatal) infection or make any infection you have worse. Tell your doctor right away if you have any signs of infection (such as sore throat that doesn't go away, fever, chills, and cough).

Tell your doctor right away if you have any serious side effects, such as: weakness, puffy face, muscle pain/cramps, unusual weight gain, slow wound healing, thinning skin, bone/joint pain, mental/mood changes (such as depression, mood swings, agitation), easy bruising/bleeding, vision problems, swelling ankles/feet/hands, fast/slow/irregular heartbeat, unusual hair/skin growth.

**OVERDOSAGE**

Treatment of acute over-dosage is by supportive and symptomatic therapy. For chronic over-dosage 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.

**Storage: - Store below 25°C. Protected from Light and moisture.**

**Improper Storage may deteriorate the product**

**Medicine: - Keep out of reach of children.**

**Presentation:** - Each pack contain Hydrocortisone Sodium Succinate injection IP one vial and a Ampoule of 5 ml of sterile water for injection IP


Manufactured by:

AMERICAN REMEDIES©
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)
ICO: American Remedies LLC, DE, USA

Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in





SIZE L 80 x H 150 MM


For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

# ℞ Hydrocortisone Sodium Succinate Injection I.P.

# Cortican

Injection **100 mg**

For I.M/I.V. USE ONLY

**Composition:-**

Each Vial Contains:-

| | |
|---|---|
| Hydrocortisone Sodium Sucinate (Sterile) | I.P. |
| Eq. to Hydrocortisone | 100 mg. |

**Description**

Hydrocortisone Sodium Succinate Sterile Powder is an anti-inflammatory glucocorticoid, which contains hydrocortisone sodium succinate as the active ingredient. Hydrocortisone Sodium Succinate Sterile Powder for intravenous or intramuscular administration.

The chemical name for hydrocortisone sodium succinate is pregn-4-ene-3,20-dione,21-(3carboxy-loxopropoxy)-11,17-dihydroxy-, monosodium salt, (11β)-, and its molecular weight is 484.51. The structural formula is represented below:


**Hydrocortisone Sodium Sccinate**

Hydrocortisone sodium succinate is a white or nearly white, odorless, hygroscopic amorphous solid. It is very soluble in water and in alcohol, very slightly soluble in acetone and insoluble in chloroform.

**PHARMACOLOGY**

**Pharmacokinetics**

Hydrocortisone is readily absorbed from the gastrointestinal tract and peak blood concentrations are attained in about an hour. The plasma half-life is about 100 minutes. It is more than 90% bound to plasma proteins. Following intramuscular injection, the absorption of the water-soluble sodium phosphate and sodium succinate esters is rapid, while absorption of hydrocortisone free alcohol and its lipid-soluble esters is slower. Absorption of hydrocortisone acetate after intra-articular or soft-tissue injection is also slow. Hydrocortisone is absorbed through the skin, particularly in denuded areas.

Hydrocortisone is metabolised in the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, with a very small proportion of unchanged hydrocortisone. Hydrocortisone readily crosses the placenta.

**Precautions**

Before using this medication, tell your doctor or pharmacist your medical history, especially of: bleeding problems, blood clots, bone loss (osteoporosis), diabetes, certain eye diseases (such as cataracts, glaucoma, herpes infection of the eye), heart problems (such as heart failure, recent heart attack), high blood pressure, current/past infections (such as those caused by fungus, herpes, tuberculosis, threadworm), kidney disease, liver disease, mental/mood conditions (such as psychosis, anxiety, depression), stomach/intestinal problems (such as diverticulitis, ulcer, ulcerative colitis), seizures, thyroid problems, mineral imbalance (such as low levels of potassium or calcium in the blood).

This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Talk to your doctor if you are using marijuana (cannabis).

**Nursing Mothers:**

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from corticosteroids, a decision should be made whether to continue nursing, or discontinue the drug, taking into account the importance of the drug to the mother.

**Uses and Administration**

Hydrocortisone is a corticosteroid with both glucocorticoid and to a lesser extent mineralocorticoid activity. As cortisol it is the most important of the predominantly glucocorticoid steroids secreted by the adrenal cortex. Hydrocortisone is used, usually with a more potent mineralocorticoid, for replacement therapy in adrenocortical insufficiency. It may also be used for its glucocorticoid properties in other conditions for which corticosteroid therapy is indicated but drugs with fewer mineralocorticoid effects tend to be preferred for the long-term systemic therapy of auto-immune and inflammatory disease. The dose may be expressed in terms of the base, and the following are each equivalent to about 100 mg of hydrocortisone:

However, esterification generally alters potency and compounds with equivalent hydrocortisone content may not have equivalent clinical effect. When given **orally** hydrocortisone free alcohol is usually used; the cipionate ester is used in some formulations. For **replacement therapy** in acute or chronic adrenocortical insufficiency the normal requirement is 20 to 30 mg daily (usually taken in 2 doses, the larger in