

Prescribing Information

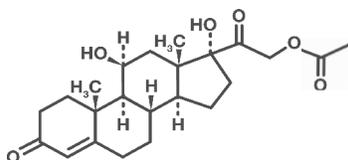
NOVACORT® gel

DESCRIPTION

Each gram of NOVACORT contains 2.0% (20 mg) Hydrocortisone Acetate and 1.0% (10 mg) Pramoxine Hydrochloride (HCl). Other Ingredients: Aloe Polysaccharides, Benzyl Alcohol, Biopeptide CL, Cetyl Alcohol, Dimethicone, Dimethyl Isosorbide, Glycerin, Glyceryl Stearate, Hydroxypropyl Methylcellulose, PEG-100 Stearate, Phenoxyethanol, Poloxamer 407, Propylene Glycol, Purified Water, Stearoyltrimethylsilane, Stearyl Alcohol, and Witch Hazel Distillate.

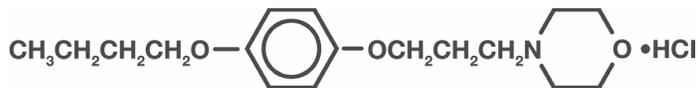
Hydrocortisone Acetate

Hydrocortisone Acetate is a topical corticosteroid anti-inflammatory and anti-pruritic agent. Chemically, Hydrocortisone Acetate is [Pregn-4-ene-3, 20-dione, 21-(acetyloxy)-11, 17-dihydroxy-, (11-beta)-C₂₃H₃₂O₆] with a molecular weight of 404.50. Chemically, Hydrocortisone Acetate is represented by the following structural formula:



Pramoxine Hydrochloride

Pramoxine Hydrochloride (Pramoxine HCl) is a topical anesthetic agent. Chemically, Pramoxine Hydrochloride is [4-(3-(p-butoxyphenoxy)propyl) morpholine Hydrochloride C₁₇H₂₇NO₃ • HCl] with a molecular weight of 329.87. Chemically, Pramoxine Hydrochloride is represented by the following structural formula:



CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, anti-pruritic, and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pramoxine Hydrochloride is a topical anesthetic agent which provides temporary relief from itching and pain. It acts by stabilizing the neuronal membrane of the nerve endings with which it comes into contact.

Pharmacokinetics

The extent of percutaneous absorption of topical steroids is determined by many factors including the vehicle, the integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption of topical corticosteroids. Occlusive dressings substantially increase the percutaneous

absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See DOSAGE AND ADMINISTRATION.)

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids.

Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS AND PRECAUTIONS

General

For external use only. Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of a potent topical steroid applied over a large surface area and under an occlusive dressing should be evaluated periodically for the evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is usually prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See WARNINGS AND PRECAUTIONS-Pediatric Use.) Keep out of reach of children.

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. Burning, itching, irritation, and dryness have been reported infrequently following the use of topical corticosteroids.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient:

Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressing.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests:

The following tests may be helpful in evaluating the HPA axis suppression: (1) Urinary free cortisol test; and (2) ACTH stimulation test.

Carcinogenesis, Mutagenesis, and Impairment of Fertility:

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and Hydrocortisone have revealed negative results.

Pregnancy. Teratogenic Effects. Category C:

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers:

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable amounts in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities NOT likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use:

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include; bulging fontanelles, headaches, and bilateral papilledema.

Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infections, skin atrophy, striae, and miliaria. Possible local adverse reactions associated with pramoxine include burning and stinging.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See WARNINGS AND PRECAUTIONS.)

DOSAGE AND ADMINISTRATION

Topical corticosteroids are generally applied to the affected area as a thin film three to four times daily (depending on the severity of the condition) in accordance with physician's directions or as directed otherwise by a physician. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

Use with occlusive dressings or diapers should be under physician supervision.

HOW SUPPLIED

NDC #69646-704-26 29.0 gram gel tube with separate applicator tip for use if and as directed by your physician. After each use, remove and wash applicator tip thoroughly.

NDC #69646-704-02 2.0 gram gel sample – not for resale

NDC #69646-704-08 10-count carton of 2.0 gram gel sample packs – not for resale

NDC #69646-704-01 1.0 gram gel sample – not for resale

NDC #69646-704-38 10-count carton of 1.0 gram gel sample packs – not for resale

NDC # 69646-704-03: 2.0 gram gel tube sample – not for resale

NDC # 69646-704-11: 10-count carton of 2.0 gram gel sample tubes – not for resale

Each 1.0 gram gel pack contains multiple doses depending on the surface area treated.

Each 2.0 gram gel pack or tube contains multiple doses depending on the surface area treated.

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

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