

Composition

Pracort ® Cream: Each gm of Pracort ® cream contains 10 mg Pramoxine HCl USP and 25 mg Hydrocortisone acetate BP.

Pracort ® Ointment: Each gm of Pracort ® ointment contains 10 mg Pramoxine HCl USP and 25 mg Hydrocortisone acetate BP.

Clinical Pharmacology

Hydrocortisone acetate is a topical corticosteroid. Topical corticosteroids have 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 the 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 nerve endings with which it comes into contact.

Indications and Usage

Pracort is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

It can be used for minor skin irritations, anal itching or hemorrhoids, insect bites etc.

Contraindications

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

Precautions

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.

Use in pregnancy

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.

Lactating mother

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.

Side effect

No serious systemic side effects are expected from the use of hydrocortisone and Pramoxine topical unless a large amount of the medication is used for a long period of time. If the drug is being absorbed into the system, you may experience blurred vision, halos around lights, an irregular heartbeat, insomnia, mood changes, weight gain, or fatigue.

Less serious side effects are more likely to occur. These are redness, burning, itching, or irritation at the application site.

Dosage and Administration

Pracort ® should be generally applied to the affected area as a thin film for three to four times daily depending on the severity of the condition.

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.

Drug Interaction

Do not use other topical medications on the affected area during treatment with hydrocortisone and Pramoxine topical without first talking to the doctor.

Storage Conditions

Store in a cool and dry place protected from light.

HOW SUPPLIED

Pracort ® Cream : Each pack has a tube containing 10 gm of the cream.

Pracort ® Ointment : Each pack has a tube containing 10 gm of the ointment.