1.85% hydrocortisone acetate – 1.15% pramoxine HCl

ProCort® is the only hemorrhoid treatment containing Invisicare®, a patented* M1 Polymer delivery system which holds active ingredients on the skin longer.

Fast Acting Dual Action Relief

• Hydrocortisone acetate 1.85%
  – Anti-Inflammatory Stops the Burning and Itching

• Pramoxine HCl 1.15%
  – Anesthetic Alleviates Pain

• Provides the Dual Action of a Proven Anti-Inflammatory Agent and Topical Anesthetic Without the Risk of Caine-Like Sensitization

Long Lasting Relief

• Contains Invisicare® M1 Polymer
  – Bonds and Delivers the Active Ingredients on the Skin up to 4 Hours.¹
  – ProCort® is specifically formulated with a combination of hydrophobic and hydrophilic polymers that carry water insoluble active ingredients in water-based products without the use of alcohol, silicones, waxes, or other organic solvents.
  – The technology is non-occlusive and allows normal skin respiration and perspiration while moisturizing and protecting against exposure from a wide variety of environmental irritants.

Comfortable Relief

• Patient Friendly Tapered Applicators with Multiple Delivery Ports

• Non-Greasy Cream with No Unpleasant Scent

Convenient and Economical

• ProCort® Kits are Packaged for Ease of Use; at Home or Away
  – Each ProCort® Kit Contains (1) 60gm Tube and (15) Disposable Tapered Applicators

* Invisicare® Patent Numbers: 7,674,471, 6,756,059, 6,582,683

¹Applied Consumer Services (ACS) Study #6771-X
DESCRIPTION:

ProCort® is a topical preparation containing hydrocortisone acetate 1.85% and pramoxine hydrochloride 1.15% in a hydrophilic and hydrophobic cream base which contains patented *Inviscare M1 polymer technology.

Active Ingredients: Hydrocortisone Acetate 1.85%, Pramoxine HCL 1.15%


Topical corticosteroids are anti-inflammatory and anti-pruritic agents. The structural formula, the chemical name, molecular formula and molecular weight for active ingredients are presented below:

![Chemical Structure](image)

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 a 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 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.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids 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. 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 topical 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.

PRECAUTIONS:

General: 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 to a large surface area and under an occlusive dressing should be evaluated periodically for 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 generally 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 Precautions-Pediatric Use.) If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. 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 occluded unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressings.
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.

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, skin irritation, dermatitis, hypertrichosis, hyperpigmentation, acneiform eruptions, and morphea-like conditions. Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects. (See PRECAUTIONS.)

DOSEAGE 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. Occlusive dressings may be used for the management of persistent or recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

DIRECTIONS FOR RECTAL ADMINISTRATION:

1. To open, remove foil tab or puncture foil seal with cap.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. Securely apply screw cap on tube.
4. Gently insert the applicator into rectum and squeeze tube again to force the required amount of cream into rectum.
5. Securely apply screw cap on tube.
6. Securely apply screw cap on tube.

HOW SUPPLIED: Hydrocortisone Acetate 1.85%, Pramoxine HCl 1.15% is a topical cream and supplied in the following:

60 gram Tube Kit (NDC# 50967-357-60), each containing a 60 gm tube and 15 single-use applicators.
2 gram Sample Kit (NDC# 50967-357-02), each containing a 2 gm tube and 1 single-use applicator.

ProCort® Storage Conditions: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Rx only

Distributed by: Women's Choice Pharmaceuticals, Gilbert, AZ 85233 (877) 774-4949 www.wcpharma.com

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Long Lasting Results

Holds The Active Ingredients on the Skin

Up to 4 Hours