

## **HYDROXATE GEL- hydrocortisone 2% gel** **PureTek Corporation**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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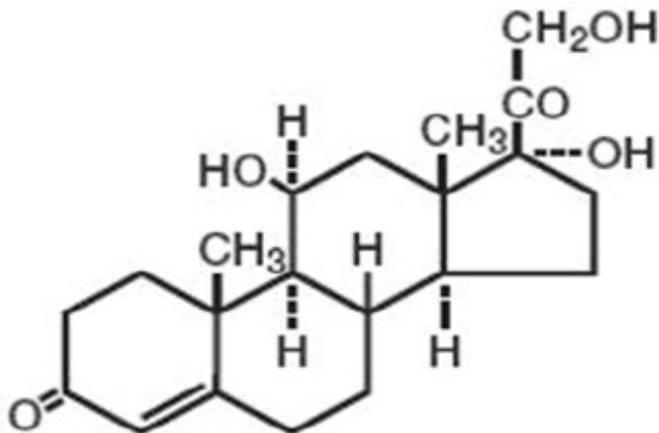
### **Hydroxate™ Gel**

#### **Rx only**

#### **DESCRIPTION**

Each gram of Hydroxate™ Gel contains 20 mg of hydrocortisone. Inactive ingredients include: Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Ethylhexylglycerin, Hydroxyethyl Cellulose, PEG-4, Phenoxyethanol, Propylene Glycol. Chemically,

hydrocortisone is [Pregn-4-ene-3,20-dione,11,17,21-trihydroxy-, (11 $\beta$ 17 $\beta$ 21 $\beta$ )]with the molecular formula (C<sub>21</sub>H<sub>30</sub>O<sub>5</sub>) and is represented by the following structural formula:



Its molecular weight is 362.47 and its CAS Registry Number is 50-23-7. The topical corticosteroids, including hydrocortisone, constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

#### **CLINICAL PHARMACOLOGY**

##### **Mechanism of Action-**

Topical corticosteroids share anti-inflammatory, antipruritic, and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the 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.

##### **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 dermatosis.

## **CONTRAINDICATIONS**

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

## **WARNINGS:**

**For external use only. Not for ophthalmic use.**

## **PRECAUTIONS**

**Do not use over large areas of the body longer than one week unless directed by a licensed healthcare practitioner.**

### **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 or 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 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:

Urinary free cortisol test  
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:*

Pregnancy 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 quantities 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 pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients 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 pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

### **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 infection, skin atrophy, striae, and miliaria.

### **OVERDOSAGE**

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

### **DOSAGE AND ADMINISTRATION**

Topical corticosteroids are generally applied to the affected area not more than two 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 and appropriate antimicrobial therapy instituted.

**Use under the direction of a licensed healthcare practitioner.**

### **HOW SUPPLIED:**

**Hydroxate™ Gel** is available as follows: 1 oz. (28 g) tube (NDC 59088-328-03)

**Do not use if tube seal is broken.**

**KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.**

Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature].

## Hydroxate™ Gel

DERMACINRx

NDC 59088-328-03

Rx Only

# Hydroxate™ Gel

Hydrocortisone 2%, contains Aloe

Anti-Inflammatory/Anti-Itch Gel

NET WT. 1oz (28 g)

Use under the direction of a licensed healthcare practitioner.

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

**ACTIVE INGREDIENT:** Hydrocortisone 2%

**INACTIVE INGREDIENTS:** Aloe Barbadensis (Aloe Vera) Leaf Juice, Aqua (Purified Water), Ethylhexylglycerin, Hydroxyethyl Cellulose, PEG-4, Phenoxyethanol, Propylene Glycol.

**INDICATIONS:** Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatosis.

**DOSAGE:** Apply to affected area not more than 2 to 4 times daily or as directed by a licensed healthcare practitioner. See insert for complete product information. Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

**WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

Do not use on wounds, damaged skin or with a heating pad. Use with care during pregnancy. If irritation or sensitivity occurs or infection appears, discontinue use.

See enclosed insert(s) for full prescribing information.

Manufactured in the USA by:  
**PureTek Corporation**  
Panorama City, CA 91402  
For questions or information  
call toll-free: 877-921-7873



List No. 32803IFA Rev.38927



## HYDROXATE GEL

hydrocortisone 2% gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-328
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	20 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>HYDROXYETHYL CELLULOSE, UNSPECIFIED</b> (UNII: T4V6TWG28D)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYETHYLENE GLYCOL 200</b> (UNII: R95B8J264J)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
<b>1</b>	NDC:59088-328-03	28 g in 1 TUBE; Type 0: Not a Combination Product	03/15/2024	

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		03/15/2024	

**Labeler** - PureTek Corporation (785961046)

Revised: 3/2024

PureTek Corporation