

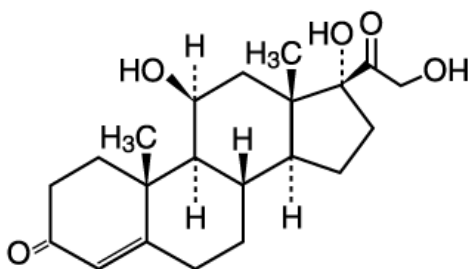
## Vytone<sup>®</sup> Cream 1%

(hydrocortisone-iodoquinol)

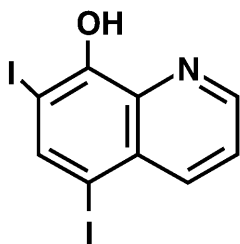
### DESCRIPTION

Each gram of Vytone<sup>®</sup> Cream 1% contains 10 mg of hydrocortisone and 10 mg of iodoquinol in a greaseless base of purified water, propylene glycol, glyceryl monostearate SE, cholesterol and related sterols, isopropyl myristate, polysorbate 60, cetyl alcohol, sorbitan monostearate, polyoxyl 40 stearate, sorbic acid, and polysorbate 20.

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



and iodoquinol, 5,7-diiodo-8-quinolinol (C<sub>9</sub>H<sub>5</sub>I<sub>2</sub>NO) is represented by the following structure:



Hydrocortisone is an anti-inflammatory and antipruritic agent, while iodoquinol is an antifungal and antibacterial agent.

### CLINICAL PHARMACOLOGY

Hydrocortisone has anti-inflammatory, antipruritic and vasoconstrictor properties. The mechanism of anti-inflammatory activity is unclear. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Iodoquinol has both antifungal and antibacterial properties.

**Pharmacokinetics:** The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Hydrocortisone can be absorbed from normal intact skin. Inflammation and/or other inflammatory disease processes in the skin increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, hydrocortisone is metabolized 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, together with a very small proportion of unchanged hydrocortisone.

There are no data available regarding the percutaneous absorption of iodoquinol; however, following oral administration, 3-5% of the dose was recovered in the urine as a glucuronide.

#### **INDICATIONS AND USAGE**

Based on a review of a related drug by the National Research Council and subsequent FDA classification for that drug, the indications are as follows: "Possibly" Effective: Contact or atopic dermatitis; impetiginized eczema; nummular eczema; infantile eczema; endogenous chronic infectious dermatitis; stasis dermatitis; pyoderma; nuchal eczema and chronic eczematooid otitis externa; acne urticata; localized or disseminated neurodermatitis; lichen simplex chronicus; anogenital pruritus (vulvae, scroti, ani); folliculitis, bacterial dermatoses; mycotic dermatoses such as tinea (capitis, cruris, corporis, pedis); moniliasis, intertrigo. Final classification of the less-than-effective indications requires further investigation.

#### **CONTRAINDICATIONS**

Vytone Cream is contraindicated in those patients with a history of hypersensitivity to hydrocortisone, iodoquinol or any other components of the preparation.

#### **WARNINGS AND PRECAUTIONS**

For external use only. Keep away from eyes. If irritation develops, the use of Vytone Cream should be discontinued and appropriate therapy instituted. Staining of the skin and fabrics may occur. If extensive areas are treated or if the occlusive technique is used, the possibility exists of increased systemic absorption of the corticosteroid, and suitable precautions should be taken. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. 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. Iodoquinol may be absorbed through the skin and interfere with thyroid function tests. If such tests are contemplated, wait at least one month after discontinuance of therapy to perform these tests. The ferric chloride test for phenylketonuria (PKU) can yield a false positive result if iodoquinol is present in the diaper or urine.

Prolonged use may result in overgrowth of non-susceptible organisms requiring appropriate therapy. Keep out of reach of children.

**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 hydrocortisone or iodoquinol.

*In vitro* studies to determine mutagenicity with hydrocortisone have revealed negative results. Mutagenicity studies have not been conducted with iodoquinol.

**Pregnancy Category C:** Animal reproductive studies have not been conducted with Vytone Cream. It is not known whether Vytone Cream can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Vytone Cream should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Vytone Cream is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients under the age of 12 have not been established.

### **ADVERSE REACTIONS**

The following local adverse reactions are reported infrequently with topical corticosteroids. These reactions are listed in an approximate decreasing order of occurrence:

Burning	Allergic contact dermatitis
Itching	Maceration of the skin
Irritation	Secondary infection
Dryness	Skin atrophy
Folliculitis	Striae
Hypertrichosis	Miliaria
Acneiform eruptions	
Hypopigmentation	
Perioral dermatitis	

### **DOSAGE AND ADMINISTRATION**

Apply to affected area 3 to 4 times daily in accordance with physician's directions.

### **HOW SUPPLIED**

1% –Tube 1 oz NDC 0066-0051-01

Store at room temperature. Keep tightly closed.

Prescribing Information as of September 2006.

### **Rx ONLY**

Manufactured for:

### **Dermik Laboratories**

a business of sanofi-aventis U.S. LLC

Bridgewater, NJ 08807