HYDROCORTISONE- hydrocortisone cream
Teligent Pharma, Inc.

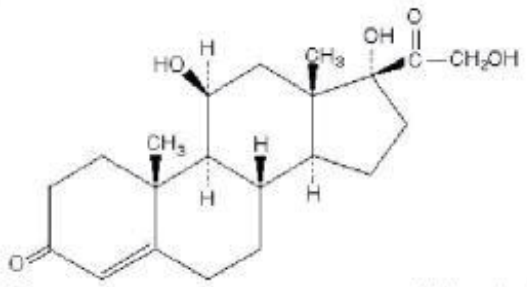
HYDROCORTISONE CREAM USP, 2.5%

Rx only

For Dermatologic Use Only
Not For Ophthalmic Use

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Hydrocortisone Cream 2.5% contains hydrocortisone. Hydrocortisone is a white to practically white crystalline powder. Chemically, hydrocortisone is pregn-4-ene-3,20-dione, 11, 17,21-trihydroxy-, (11β)-. The structural formula of hydrocortisone is:



Molecular Formula: $C_{21}H_{30}O_5$ Molecular Weight: 362.47

Each gram of the 2.5% cream contains 25 mg of hydrocortisone in a base of glyceryl monostearate, polyoxyl 40 stearate, glycerin, paraffin, stearyl alcohol, isopropyl palmitate, sorbitan monostearate, potassium sorbate, lactic acid, methylparaben, propylparaben, and purified water.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, anti-pruritic 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 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 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.

Recover 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 so 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 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 product 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 women.

Pediatric Use

Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal (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 to 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.

To report **SUSPECTED ADVERSE REACTIONS**, contact Teligent Pharma, Inc. at 1-856-697-1441, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Apply to the affected area as a thin film 2 to 4 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.

HOW SUPPLIED

Hydrocortisone Cream USP, 2.5%, is a white cream available in the following sizes:

30 gram tube	NDC 52565-004-30
1 lb. jar (453.6 grams)	NDC 52565-004-26

Store at 20° to 25°C (68° to 77°F) excursions permitted between 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].

Manufactured by:
Teligent Pharma, Inc.
Buena, NJ 08310

PI-004-00
Rev 06/2019

PRINCIPAL DISPLAY PANEL - 453.6 g Jar Carton

NDC 52565-004-26

Hydrocortisone
Cream USP, 2.5%

Net Wt 453.6 g (1 Lb)

Rx Only

For Dermatological Use Only
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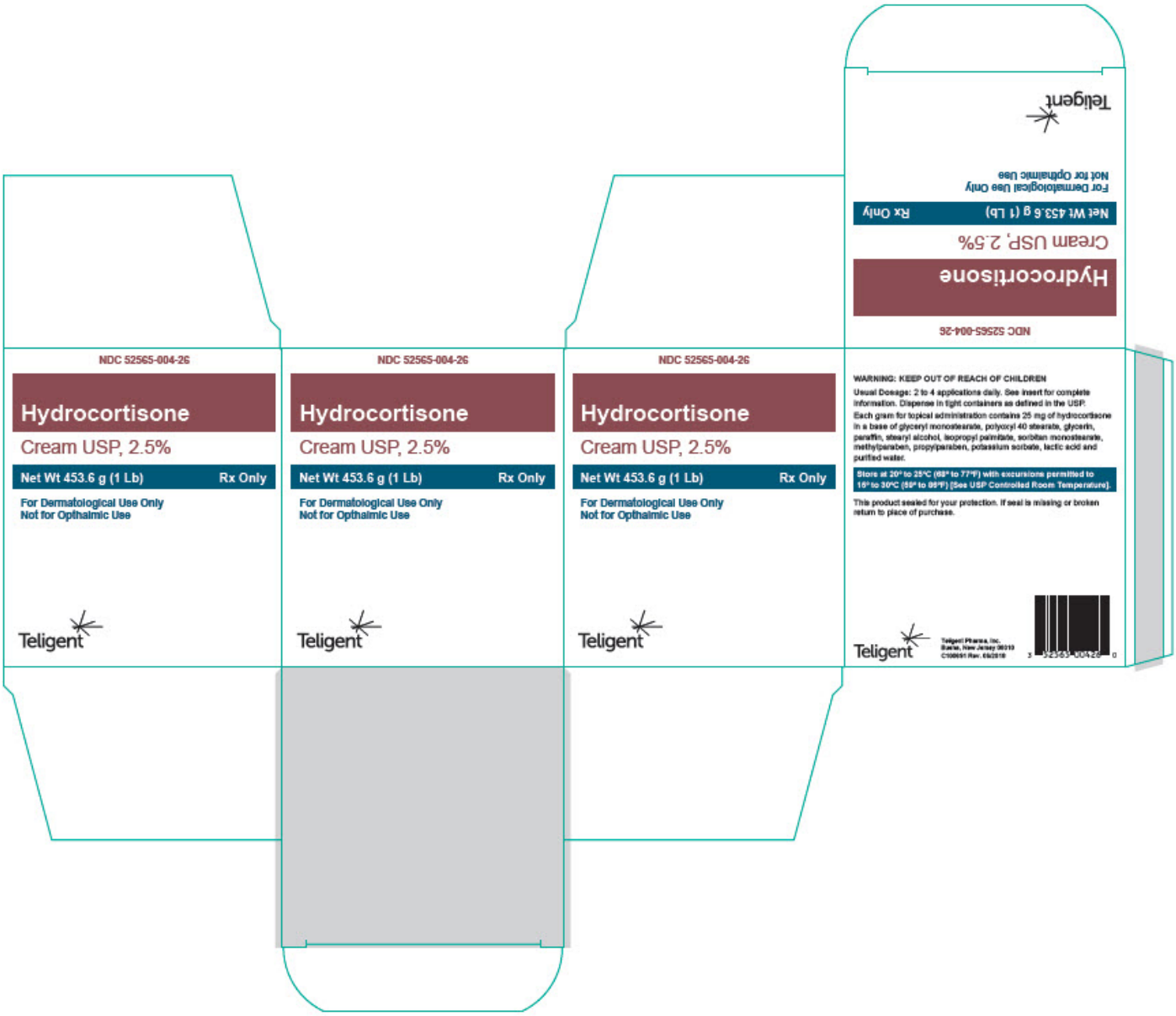


PRINCIPAL DISPLAY PANEL - 30 gram Carton

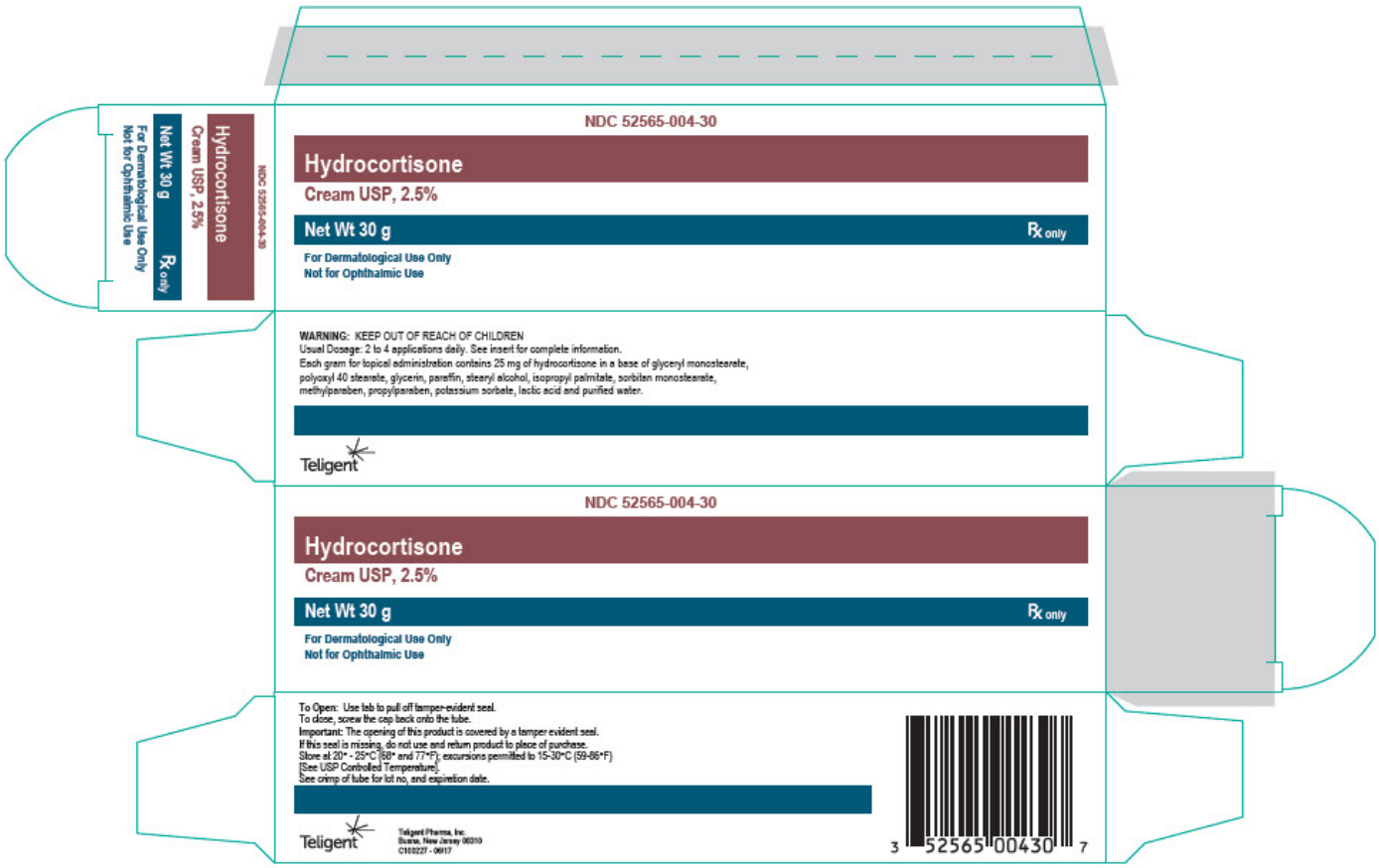
NDC 52565-004-30

Hydrocortisone
Cream USP, 2.5%

Net Wt. 30 g

For Dermatological Use Only.
Not for Ophthalmic Use.

Rx only



HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52565-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	25 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
glyceryl monostearate (UNII: 230OU9XXE4)	
polyoxyl 40 stearate (UNII: 13A4J4NH9I)	
glycerin (UNII: PDC6A3C0OX)	
paraffin (UNII: I9O0E3H2ZE)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
sorbitan monostearate (UNII: NVZ4I0H58X)	
potassium sorbate (UNII: 1VPU26JZZ4)	

lactic acid (UNII: 33X04XA5AT)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52565-004-30	1 in 1 CARTON	07/23/2018	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52565-004-26	1 in 1 CARTON	07/23/2018	
2		453.6 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203810	07/23/2018	

Labeler - Teligent Pharma, Inc. (011036910)

Establishment

Name	Address	ID/FEI	Business Operations
Teligent Pharma, Inc.		011036910	manufacture(52565-004)

Revised: 7/2018 Teligent Pharma, Inc.