

## **DESOXIMETASONE - desoximetasone cream** **Viona Pharmaceuticals Inc**

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**Desoximetasone Cream USP, 0.25%**

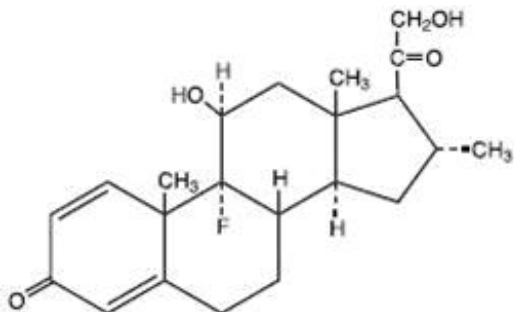
**FOR DERMATOLOGIC USE ONLY. NOT FOR USE IN EYES.**

### **DESCRIPTION**

Desoximetasone Cream USP, 0.25% contains the active synthetic corticosteroid desoximetasone, USP. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Each gram of desoximetasone cream USP, 0.25% contains 2.5 mg of desoximetasone, USP in an emollient cream consisting of cetostearyl alcohol, edetate disodium dihydrate, isopropyl myristate, lanolin alcohols, mineral oil, purified water and white petrolatum.

The chemical name of desoximetasone is Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-, (11 $\beta$ ,16 $\alpha$ )-. Desoximetasone has the molecular formula C<sub>22</sub>H<sub>29</sub>FO<sub>4</sub> and a molecular weight of 376.47. The CAS Registry Number is 382-67-2. The structural formula is:



### **CLINICAL PHARMACOLOGY**

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.

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.

Pharmacokinetic studies in men with desoximetasone cream, 0.25% with tagged desoximetasone showed a total of  $5.2\% \pm 2.9\%$  excretion in urine ( $4.1\% \pm 2.3\%$ ) and feces ( $1.1\% \pm 0.6\%$ ) and no detectable level (limit of sensitivity: 0.005 mcg/mL) in the blood when it was applied topically on the back followed by occlusion for 24 hours. Seven days after application, no further radioactivity was detected in urine or feces. The half-life of the material was  $15 \pm 2$  hours (for urine) and  $17 \pm 2$  hours (for feces) between the third and fifth trial day. Studies with other similarly structured steroids have shown that predominant metabolite reaction occurs through conjugation to form the glucuronide and sulfate ester.

## **INDICATIONS AND USAGE**

Desoximetasone cream, 0.25% is 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.

## **WARNINGS**

Desoximetasone cream, 0.25% is not for ophthalmic use.

**Keep out of reach of children.**

## **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. 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.

Pediatric patients 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 hypothalamic-pituitary-adrenal (HPA) axis suppression: Urinary free cortisol test and ACTH stimulation test

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of desoximetasone.

Desoximetasone was nonmutagenic in the Ames test.

### **Pregnancy Category**

Teratogenic Effects

Pregnancy Category C

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been

shown to be teratogenic after dermal application in laboratory animals.

Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 3 to 30 times the human dose of desoximetasone cream, 0.25% and 15 to 150 times the human dose of desoximetasone cream, 0.05%, or desoximetasone gel, 0.05%.

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, desoximetasone cream, 0.25% 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 breastmilk. Systemically administered corticosteroids are secreted into breastmilk 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.**

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.

In controlled clinical studies the incidence of adverse reactions was low (0.8%) for desoximetasone cream, 0.25% and included burning, folliculitis, and folliculo-pustular lesions. The incidence of adverse reactions was also 0.8% for desoximetasone cream, 0.05% and included pruritus, erythema, vesiculation, and burning sensation.

## **OVERDOSAGE**

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

## **DOSAGE AND ADMINISTRATION**

Apply a thin film of desoximetasone cream USP, 0.25% to the affected skin areas twice daily. Rub in gently.

## **HOW SUPPLIED**

Desoximetasone Cream USP, 0.25% is supplied in 15 gram, 60 gram and 100 gram tubes.

NDC 72578-091-01 in tube of 15 gm

NDC 72578-091-02 in tube of 60 gm

NDC 72578-091-03 in tube of 100 gm

## **Storage**

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

**Keep this and all medications out of the reach of children.**

**Call your doctor for medical advice about side effects. You may report side effects to Viona Pharmaceuticals Inc. at 1-888-304-5011 or FDA at 1-800-FDA-1088.**

**Manufactured by:**

**Zydus Lifesciences Ltd.**

Changodar, Ahmedabad, India

**Distributed by:**

**Viona Pharmaceuticals Inc.**

Cranford, NJ 07016

Rev.: 08/22

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 72578-091-01 in tube of 15gm

Desoximetasone Cream USP, 0.25%

Rx only

15 gm

NDC 72578-091-01

## Desoximetasone Cream, USP

**0.25%**

FOR TOPICAL USE ONLY. NOT FOR ORAL, OPHTHALMIC, OR INTRAVAGINAL USE.  
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**15 g**  
Rx only

**VIONA**

Each gram contains: 2.5 mg of desoximetasone, USP in an emollient cream base consisting of cetostearyl alcohol, edetate disodium dihydrate, isopropyl myristate, lanolin alcohols, mineral oil, purified water and white petrolatum.  
**Usual dosage:** Apply a thin film to affected skin area twice daily. Rub in gently.  
 See package insert for full prescribing information.  
 Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F).  
 [see USP Controlled Room Temperature].  
 To open: Remove cap. Turn cap upside down and place puncture tip onto tube.  
 Push cap until tube end is punctured. Screw cap back on to reseal tube.  
 For lot number and expiry date see crimp of tube.

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 Changodar, Ahmedabad, India

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GUJDRUGS/G25/1919  
 Rev: 08/22  
 XXXXXX

3 7 2 5 7 8 1 0 9 1 0 1 9

55.60 mm

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**Usual dosage:** Apply a thin film to affected skin area twice daily. Rub in gently. See package insert for full prescribing information.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F).  
 [see USP Controlled Room Temperature].  
**Direction for puncturing tube seal:** Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured. Screw cap back on to reseal tube.

NDC 72578-091-01

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GUJDRUGS/G25/1919  
 Rev: 08/22

3 7 2 5 7 8 1 0 9 1 0 1 9

STIN 0000000000000000  
 SN 0000000000000000  
 EXP DDMMYYYY  
 LOT XXXXXXX

ring Template

<b>DESOXIMETASONE</b>			
desoximetasone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:72578-091

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESOXIMETASONE (UNII: 4E07GXB7AU) (DESOXIMETASONE - UNII:4E07GXB7AU)	DESOXIMETASONE	2.5 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KOOR)	
PETROLATUM (UNII: 4T6H12BN9U)	

### Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72578-091-01	1 in 1 CARTON	08/31/2020	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72578-091-02	1 in 1 CARTON	08/31/2020	
2		60 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:72578-091-03	1 in 1 CARTON	08/31/2020	
3		100 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA205620	08/31/2020	

**Labeler** - Viona Pharmaceuticals Inc (081468959)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zydus Lifesciences Limited		650650802	ANALYSIS(72578-091) , MANUFACTURE(72578-091)

Revised: 10/2022

Viona Pharmaceuticals Inc