**BETAMETHASONE VALERATE- betamethasone valerate cream**
**Rebel Distributors Corp.**

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**Betamethasone Valerate**
**Cream USP, 0.1%**

**Rx only**

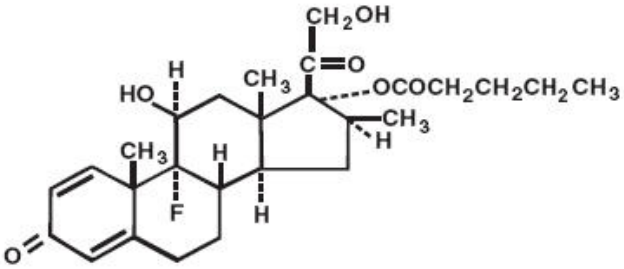
**For External Use Only. Not for Ophthalmic Use.**

## DESCRIPTION

Betamethasone Valerate Cream USP, 0.1% contains a topical corticosteroid, betamethasone valerate. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Betamethasone valerate is chemically designated as Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-17 [(1-oxopentyl) oxy], (11β, 16β)-.

MF:
$C_{27}H_{37}FO_6$
MW: 476.58




Each gram of Betamethasone Valerate Cream USP, 0.1% contains: 1.2 mg betamethasone valerate USP (equivalent to 1.0 mg betamethasone) with mineral oil, white petrolatum, ceteth-20, cetyl alcohol, stearyl alcohol, propylene glycol, phosphoric acid, sodium phosphate monobasic, sodium hydroxide, purified water and 4-chloro-m-cresol as a preservative.

## CLINICAL PHARMACOLOGY

Betamethasone valerate cream as a topical corticosteroid has 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.

Betamethasone valerate cream 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, betamethasone valerate cream is handled through pharmacokinetic

pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. They 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

Betamethasone valerate cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

## CONTRAINDICATIONS

Betamethasone valerate cream is 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.

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, use of betamethasone valerate cream 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, use of betamethasone valerate cream should be discontinued until the infection has been adequately controlled.

### Information For Patients

Patients using betamethasone valerate cream 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 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 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, betamethasone valerate cream should be used during pregnancy only if the potential benefit justifies 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 betamethasone valerate cream is 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 children receiving topical corticosteroids. Manifestations of adrenal suppression in children 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 betamethasone valerate cream to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

## 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 | Hypertrichosis | Maceration of the Skin |
| Itching | Acneiform Eruptions | Secondary Infection |
| Irritation | Hypopigmentation | Skin Atrophy |
| Dryness | Perioral Dermatitis | Striae |

| | | |
|---|---|---|
| Folliculitis | Allergic Contact Dermatitis | Miliaria |

## OVERDOSAGE

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

## DOSAGE AND ADMINISTRATION

Betamethasone Valerate Cream USP, 0.1% is generally applied to the affected skin areas one to three times daily. Dosage once or twice a day is often effective.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressing should be discontinued and appropriate antimicrobial therapy instituted.

## HOW SUPPLIED

Betamethasone Valerate Cream USP, 0.1% is supplied in 15 gram (NDC 21695-583-15) and 45 gram (NDC 21695-584-45) tubes.

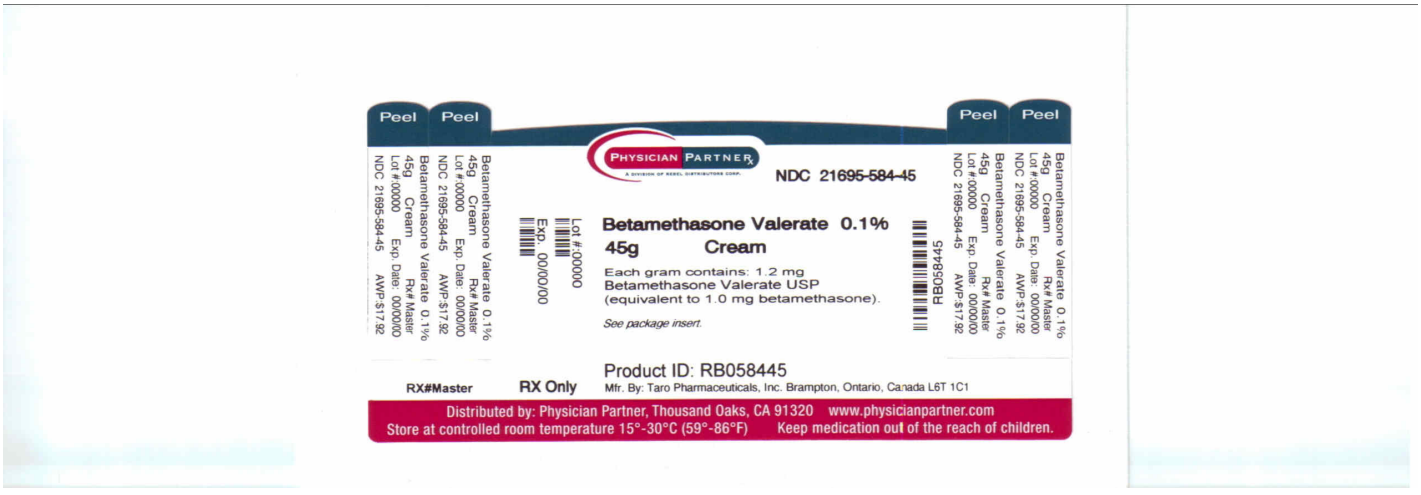
## STORAGE

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

Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

Repackaged by: Rebel Distributors Corp., Thousand Oaks, CA 91320

## Principal Display Panel




# BETAMETHASONE VALERATE

betamethasone valerate cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:21695-584(NDC:51672-1269) |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Betamethasone Valerate** (UNII: 9IFA5XM7R2) (Betamethasone - UNII:9842X06Q6M) | Betamethasone Valerate | 1 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PETROLATUM** (UNII: 4T6H12BN9U) | |
| **CETETH-20** (UNII: I835H2IHHX) | |
| **cetyl alcohol** (UNII: 936JST6JCN) | |
| **stearyl alcohol** (UNII: 2KR89I4H1Y) | |
| **propylene glycol** (UNII: 6DC9Q167V3) | |
| **phosphoric acid** (UNII: E4GA8884NN) | |
| **SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE** (UNII: 593YOG76RN) | |
| **sodium hydroxide** (UNII: 55X04QC32I) | |
| **water** (UNII: 059QF0KO0R) | |
| **CHLOROCRESOL** (UNII: 36W53O7109) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:21695-584-15 | 1 in 1 CARTON | | |
| **1** | | 15 g in 1 TUBE | | |
| **2** | NDC:21695-584-45 | 1 in 1 CARTON | | |
| **2** | | 45 g in 1 TUBE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA070062 | 05/14/1985 | |

## Labeler - Rebel Distributors Corp. (118802834)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Rebel Distributors Corp. | | 118802834 | RELABEL, REPACK |

Revised: 9/2010 Rebel Distributors Corp.