BETAMETHASONE VALERATE- betamethasone valerate lotion
STI Pharma LLC

BETAMETHASONE VALERATE LOTION USP 0.1%

(Potency expressed as betamethasone)

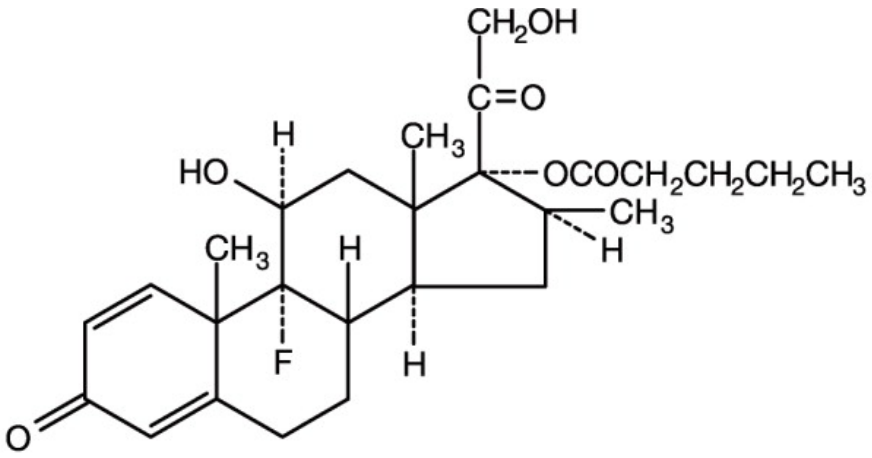
Rx Only

FOR DERMATOLOGIC USE ONLY NOT FOR OPHTHALMIC USE

DESCRIPTION:

Betamethasone Valerate Lotion contains betamethasone valerate USP, a synthetic adrenocortico-steroid for dermatologic use. Betamethasone, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity.

Betamethasone valerate is a white to practically white odorless crystalline powder practically insoluble in water, freely soluble in acetone and chloroform, soluble in alcohol, and slightly soluble in benzene and ether. Chemically, it is 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate. The structural formula is:



Molecular Formula: $C_{27}H_{37}FO_6$ Molecular Weight: 476.59

Each gram of the 0.1% Lotion contains 1.2 mg of betamethasone valerate (equivalent to 1 mg betamethasone) in a vehicle of isopropyl alcohol and water slightly thickened with carbomer 934P. Phosphoric acid or sodium hydroxide is used to adjust the pH.

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.

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 cortico-steroid-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 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 Patients: 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 that 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 dressings.
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 dressing.

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 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 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 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, 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:

Apply a few drops of Betamethasone Valerate Lotion to the affected area and massage lightly until it disappears. Apply twice daily, in the morning and at night. Dosage may be increased in stubborn cases. Following improvement, apply once daily. For the most effective and economical use, apply nozzle very

close to affected area and gently squeeze bottle.

HOW SUPPLIED

Betamethasone Valerate
Lotion USP, 0.1%
is supplied as follows:
60ml bottles NDC 54879-004-60
Shake well before using.

Store at controlled room temperature 15° - 30°C (59° - 86°F).

To report SUSPECTED ADVERSE REACTIONS, contact STI Pharma,LLC at 1-888-301-9680 or FDA at 1-800-FDA-1088 or ww.fda.gov/medwatch

Manufactured for :
STI Pharma LLC
Newtown, PA 18940

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 ML CONTAINER

NDC 54879-004-60

STI Pharma LLC

BETAMETHASONE VALERATE LOTION USP, 0.1%

(Potency expressed as betamethasone)

60ml

FOR DERMATOLOGIC USE ONLY

NOT OPHTHALMIC USE

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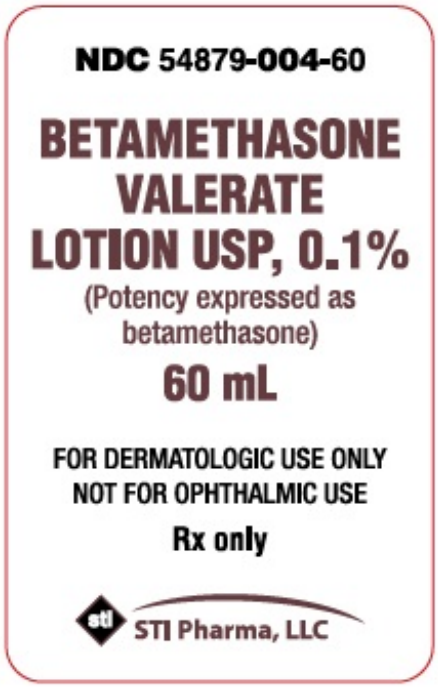

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 ML CARTON

NDC 54879-004-60

STI Pharma LLC

BETAMETHASONE VALERATE LOTION USP, 0.1%

(Potency expressed as betamethasone)

60ml

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NOT OPHTHALMIC USE

Each gram contains 1.2 mg
betamethasone valerate (equivalent
to 1 mg betamethasone) in a vehicle
of isopropyl alcohol and water slightly
thickened with carbomer 934P.
Phosphoric acid or sodium hydroxide is used
to adjust pH.

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BETAMETHASONE VALERATE

betamethasone valerate lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54879-004
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BETAMETHASONE VALERATE (UNII: 9IFA5XM7R2) (BETAMETHASONE - UNII:9842X06Q6M)	BETAMETHASONE VALERATE	1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:54879-004-60	1 in 1 CARTON	07/31/1985	
1		60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA070052	07/31/1985	

Labeler - STI Pharma LLC (832714070)

Revised: 11/2019 STI Pharma LLC