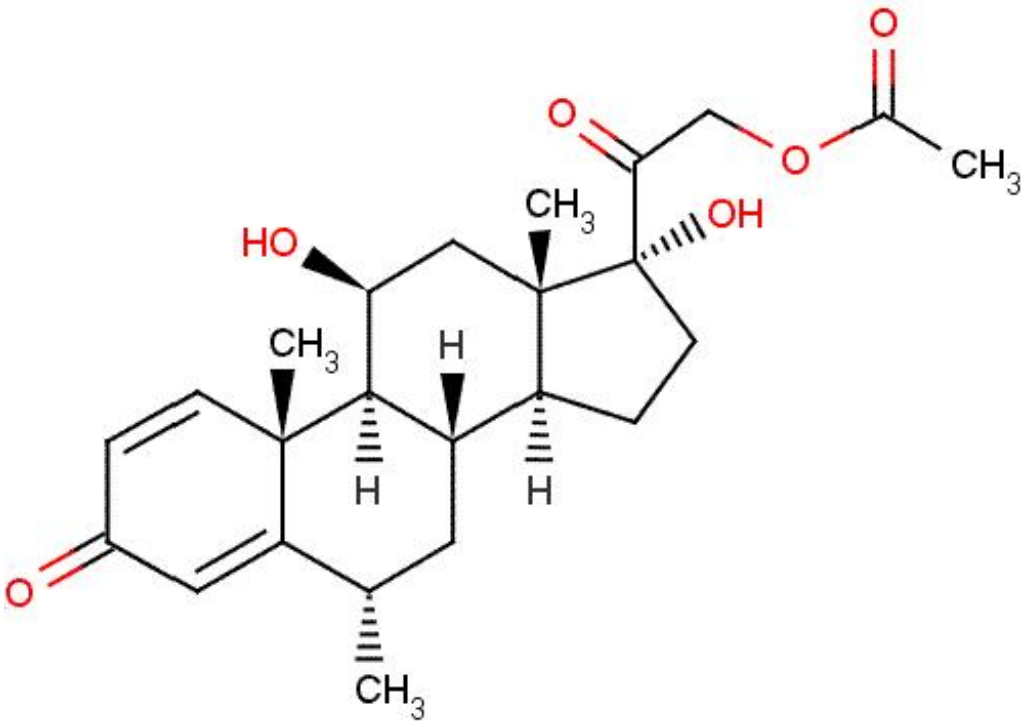
HYBRISIL - methylprednisolone acetate gel
BioZone Laboratories, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

DESCRIPTION

DESCRIPTION: The topical corticosteroids constitute a class of primary synthetic steroids used as anti-inflammatory and anti-pruritic agents. HybriSil™ Topical Silicone Gel contains methylprednisolone acetate, USP (CAS 53-36-1)
Chemical Name: Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-6-methyl-,(6α,11ß)-,11ß,17,21-Trihydroxy-6α-methylpregna-1,4-diene-3,20-dione 21-acetate. It has a molecular formula of C24H32O6 and a molecular weight of 416.51.



Contains: Methylprednisolone acetate 1.0% in a base of: silicone cross-polymers, alcohol, cyclomethicones, propylene glycol, PEG-12 glyceryl dimyristate, and benzyl alcohol.

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 vasoconstriction 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 vasoconstrictive 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 diseases 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

HybriSil™ topical gel is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, including those associated with the formation of scar tissue.

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 more potent steroid use over large surface areas, prolonged use and 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 applications, 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 proportionately larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. (See PRECAUTIONS-Pediatric Use)
This medication contains alcohol. It may produce irritation or burning sensations on open lesions. If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.
As with any topical corticosteroid product, prolonged use may produce atrophy of the skin and subcutaneous tissues. When used on intertriginous or flexor areas, or on the face, this may occur even with short-term use.
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 is prescribed.
3. Treated skin areas 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 urinary free cortisol test and the ACTH suppression test may be helpful in evaluating the HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of the effect of topical corticosteroids on fertility.
Studies to determine mutagenicity with prednisolone and hydrocortisone may 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, 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 nursing women.

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. Manifestation of intracranial hypertension include bulging fontanelles, headaches and bilateral papilledema. Administration of topical corticosteroids 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, Itching, Irritation, Dryness, Folliculitis, Hypertrichosis, Acneiform eruptions, Hypopigmentation, Perioral dermatitis, Allergic contract 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

HybriSil™ (methylprednisolone acetate 1%) silicone gel should be applied to the affected area as a thin film two or three times daily depending on the severity of the condition.
Occlusive dressings may be used for management of recalcitrant conditions. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

CAUTION

If medication accidentally gets in the eyes, wash thoroughly with water and contact a physician immediately. Keep out of the reach of children.

HOW SUPPLIED

in 30 gm bottle with pump. Prescription only.
US Patents: Pending.
Revised April 2011

Image: Bottle Label

label_cd01.jpg

Image: Carton Label

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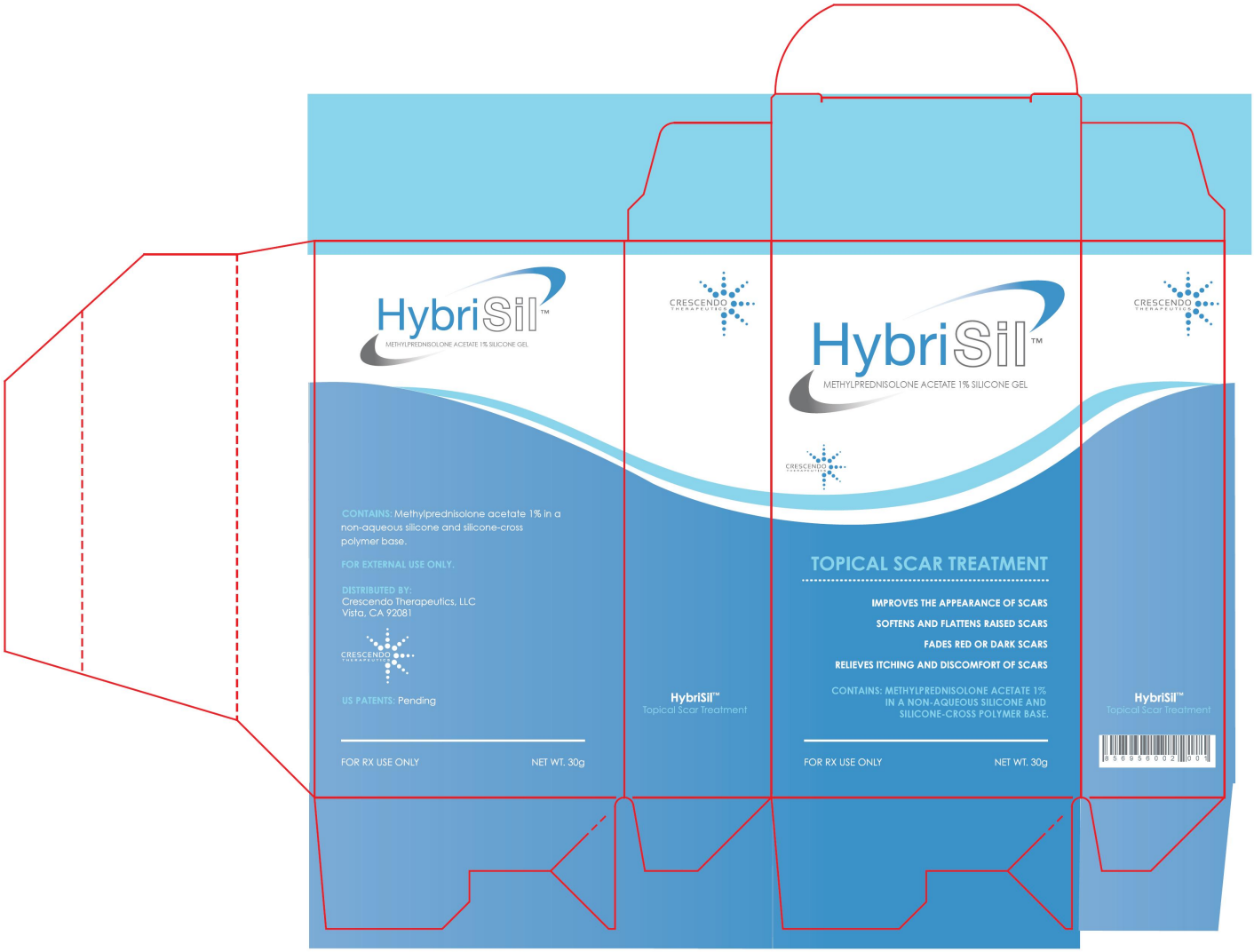

HYBRISIL

methylprednisolone acetate gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55379-405
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Methylprednisolone Acetate (UNII: 43502P7F0P) (Methylprednisolone - UNII:X4W7ZR7023)	Methylprednisolone Acetate	10 mg in 1 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55379-405-31	1 in 1 CARTON		
1	NDC:55379-405-30	30 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/05/2010	

Labeler - BioZone Laboratories, Inc. (555564293)

Revised: 4/2011 BioZone Laboratories, Inc.