AMCINONIDE- amcinonide cream
AMCINONIDE- amcinonide ointment
Taro Pharmaceuticals U.S.A., Inc.

Amcinonide Cream USP, 0.1%
Amcinonide Ointment USP, 0.1%

Rx only.

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

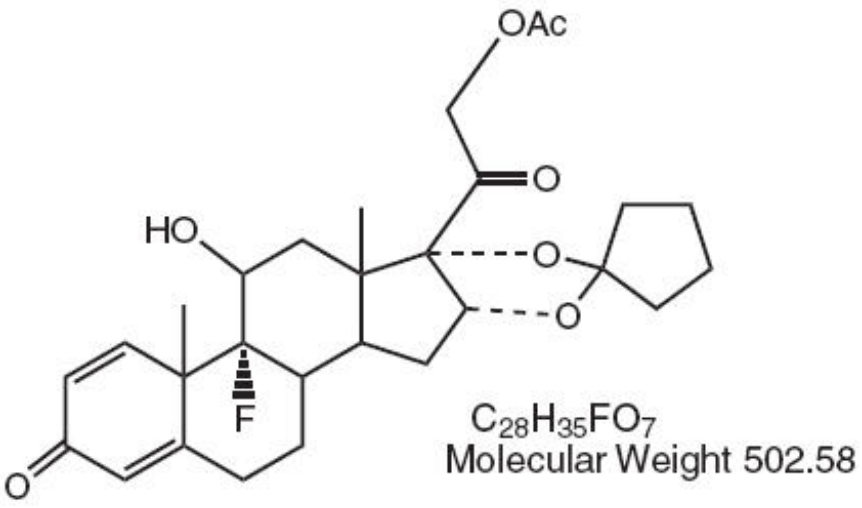
TOPICAL CREAM USP, 0.1%

Each gram of Amcinonide Cream contains 1 mg of the active steroid amcinonide in a white, smooth, homogeneous, opaque emulsion composed of benzyl alcohol (as preservative), emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water and sorbitol solution 70%.

TOPICAL OINTMENT USP, 0.1%

Each gram of Amcinonide Ointment contains 1 mg of the active steroid amcinonide in a specially formulated base composed of benzyl alcohol 2.2% (wt/wt) as preservative, butylated hydroxyanisole, citric acid anhydrous, emulsifying wax, propyl gallate, propylene glycol, and white petrolatum.

Chemically, amcinonide is:



Pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-16,17-[cyclopentylidenebis (oxy)]-9-fluoro-11-hydroxy-, (11β, 16α).

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 (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 that 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 with 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.

These products are not for ophthalmic use.

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 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 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 since 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, 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, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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 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
- Miliaria

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Topical corticosteroids are generally applied to the affected area as a thin film from two to three times daily depending on the severity of the condition.

Occlusive dressings may be a valuable therapeutic adjunct 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

Amcinonide Topical Cream USP, 0.1% (1 mg/g) is supplied in 4 gm, 15 gm, 30 gm and 60 gm tubes.

Amcinonide Topical Ointment USP, 0.1% (1 mg/g) is supplied in 15 gm, 30 gm and 60 gm tubes.

Store at 20° -25°C (68°-77°F) [see USP Controlled Room Temperature]

DO NOT FREEZE.

Mfd. By: Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel 26110

Revised: February, 2010
90056-0210-5 291

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-4054-2

30 g

Amcinonide
Cream USP, 0.1%

FOR DERMATOLOGIC USE ONLY.

NOT FOR OPHTHALMIC USE.

Rx only

TARO

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

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton

NDC 51672-4060-2

30 g

Amcinonide

Ointment USP, 0.1%

FOR DERMATOLOGIC USE ONLY.

NOT FOR OPHTHALMIC USE.

Rx only

TARO

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

AMCINONIDE

amcinonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51672-4054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Amcinonide (UNII: 423W026MA9) (Amcinonide - UNII:423W026MA9)	Amcinonide	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
benzyl alcohol (UNII: LKG8494WBH)	
glycerin (UNII: PDC6A3C0OX)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)	
water (UNII: 059QF0KO0R)	
sorbitol (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-4054-4	1 in 1 CARTON	05/31/2002	
1		4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-4054-1	1 in 1 CARTON	05/31/2002	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-4054-2	1 in 1 CARTON	05/31/2002	
3		30 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51672-4054-3	1 in 1 CARTON	05/31/2002	
4		60 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	ANDA076229	05/31/2002	

AMCINONIDE

amcinonide ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51672-4060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Amcinonide (UNII: 423W026MA9) (Amcinonide - UNII:423W026MA9)	Amcinonide	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength

benzyl alcohol (UNII: LKG8494WBH)	
butylated hydroxyanisole (UNII: REK4960K2U)	
anhydrous citric acid (UNII: XF417D3PSL)	
propyl gallate (UNII: 8D4SNN7V92)	
propylene glycol (UNII: 6DC9Q167V3)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-4060-1	1 in 1 CARTON	03/19/2003	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-4060-2	1 in 1 CARTON	03/19/2003	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-4060-3	1 in 1 CARTON	03/19/2003	
3		60 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	ANDA076367	03/19/2003	

Labeler - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Industries Ltd.		600072078	MANUFACTURE(51672-4054, 51672-4060)

Revised: 1/2020 Taro Pharmaceuticals U.S.A., Inc.