

NU-DERM TOLEREEN ANTI-PRURITIC- hydrocortisone lotion
OMP, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

OBAGI
NU-DERM®
TOLEREEN

Drug Facts

Active ingredients

Hydrocortisone, 0.5%

Purpose

Anti-itch

Uses

- Provides temporary relief of itching associated with minor skin irritations, inflammation, and rashes from:
 - Eczema
 - Psoriasis
 - Insect bites
 - Seborrheic dermatitis
 - Soaps
 - Poison ivy
 - Poison oak
 - Poison sumac
 - Jewelry
 - Cosmetics
 - Detergents
- Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

- **For external use only.**

Do not use

- In the eyes.
- For the treatment of diaper rash.

When using this product do not begin the use of any other hydrocortisone product.

Stop use and ask a doctor if

- Symptoms last for more than 7 days.
- The condition gets worse.
- Symptoms clear up and come back in a few days.

Keep out of the reach of children.

- If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years and older: apply to the affected area not more than 3 to 4 times daily.
- Children under 2 years of age, do not use, ask a doctor.

Other information

- Store at room temperature. Protect from freezing and excessive heat.

Inactive ingredients

allantoin, butylparaben, cetyl alcohol, cyclopentasiloxane, glycerin, glyceryl stearate, lactic acid, methylparaben, PEG-100 stearate, propylparaben, purified water, saponins, stearyl alcohol, tetrasodium EDTA.

Dist. by OMP, Inc., Long Beach, CA 90802

PRINCIPAL DISPLAY PANEL - 57g Bottle Carton

OBAGI

NU-DERM®

TOLEREEN

ANTI-PRURITIC

LOTION

HYDROCORTISONE

USP, 0.5%

NET WT. 2 OZ. (57g)

Drug Facts

Active ingredients	Purpose
Hydrocortisone, 0.5%	Anti-itch

Uses

- Provides temporary relief of itching associated with minor skin irritations, inflammation, and rashes from:
 - Eczema ■ Psoriasis ■ Insect bites ■ Seborrheic dermatitis
 - Soaps ■ Poison ivy ■ Poison oak ■ Poison sumac
 - Jewelry ■ Cosmetics ■ Detergents
- Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

- For external use only.

Do not use

- In the eyes.
- For the treatment of diaper rash.

When using this product do not begin the use of any other hydrocortisone product.

Stop use and ask a doctor if

- Symptoms last for more than 7 days.
- The condition gets worse.
- Symptoms clear up and come back in a few days.

Keep out of the reach of children. ■ If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years and older: apply to the affected area not more than 3 to 4 times daily.
- Children under 2 years of age, do not use, ask a doctor.

Other information

- Store at room temperature. Protect from freezing and excessive heat.

Inactive ingredients

alantoin, butylparaben, cetyl alcohol, cyclopentasiloxane, glycerin, glyceryl stearate, lactic acid, methylparaben, PEG-100 stearate, propylparaben, purified water, saponins, stearyl alcohol, tetrasodium EDTA.

Dist. by OMP, Inc., Long Beach, CA 90802
www.obagi.com Made in U.S.A. 7008 Rev. 3/06

O B A G I
N U - D E R M ®

TOLEREEN

ANTI-PRURITIC
LOTION
HYDROCORTISONE
USP, 0.5%

NET WT. 2 OZ. (57g)

NU-DERM TOLEREEN ANTI-PRURITIC
hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62032-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALLANTOIN (UNII: 344S277G0Z)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	
BUTYLPARABEN (UNII: 3QPII1U3FV8)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62032-112-36	1 in 1 BOX		
1		57 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	01/01/1988	

Labeler - OMP, Inc. (790553353)

Establishment

Name	Address	ID/FEI	Business Operations
Puretek Corporation		785961046	MANUFACTURE(62032-112) , LABEL(62032-112) , PACK(62032-112)

Revised: 10/2011

OMP, Inc.