

SOOTHE RODAN FIELDS - hydrocortisone lotion

Rodan & Fields, LLC.

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.

Rodan And Fields Hydrocortisone Lotion

HYDROCORTISONE 1%

Anti- Pruritic (Anti- Itch)

Keep out of reach of children.

if swallowed, get medical help or contact a poison control center immediately.

for external use only.

adults and children 2 years of age and older: apply to the effected area not more than 3 to 4 times daily.

children under 2 years of age: do not use, consult a doctor.

avoid contact with eyes.

if conditions worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Water, Alcohol Denat, Diisopropyl Adipate, Cyclopentasiloxane, Aluminum Starch Octenylsuccinate, Glycerin, Sodim Polyacrylate, Peg-100 Stearate, Aloe Barbadensis Leaf Juice, Astrocaryum Murumuru Butter, Serenoa Serrulata (Saw Palmetto) Fruit Extract, Cholesterol/ Potassium Sulfate, Camellia Oleifera Leaf Extract, Ceteth-20, Persea Gratissima (Avocado) Oil, Cucumis Melo (Melon) Fruit Extract, Chamomilla Recutita (Matricaria) Flower Oil, Ethylhexyl Stearate, Acetyl Glucosamine, Trehalose, Cholesterol, Linoleic Acid, Trideceth-6, Propylene Glycol, Dicaprylate, Caprylyl Glycol, Ethylhexylglycerin

Prescription for Change™

Drug Facts

Active ingredient Purpose

Hydrocortisone 1% Anti-pruritic (anti-itch)

Uses

- For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, cosmetics, and seborrheic dermatitis.
- Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

For external use only.

Avoid contact with eyes.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Do not use for the treatment of diaper rash. Consult a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center immediately.

Directions

- Adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily. ▶

Drug Facts (continued)

- Children under 2 years of age: do not use, consult a doctor.

Other information

You may report a serious adverse reaction to Rodan+Fields, Attn: Product Development, 111 Maiden Lane, Suite 400, San Francisco, CA 94108.

Inactive ingredients

Water, Alcohol Denat, Diisopropyl Adipate, Cyclopentasiloxane, Aluminum Starch Octenylsuccinate, Glycerin, Sodium Polyacrylate, Peg-100 Stearate, Aloe Barbadensis Leaf Juice, Astrocaryum Murumuru Butter, Serenoa Serrulata (Saw Palmetto) Fruit Extract, Cholesterol/Potassium Sulfate, Camellia Oleifera Leaf Extract, Ceteth-20, Persea Gratissima (Avocado) Oil, Cucumis Melo (Melon) Fruit Extract, Chamomilla Recutita (Matricaria) Flower Oil, Ethylhexyl Stearate, Acetyl Glucosamine, Trehalose, Cholesterol, Linoleic Acid, Trideceth-6, Propylene Glycol Dicaprylate, Caprylyl Glycol, Ethylhexylglycerin [In29119]

RODAN+FIELDS
SOOTHE

Dermatologist
Developed
As Needed
Hydrocortisone
Lotion

SOOTHE As Needed Hydrocortisone Lotion combines the anti-irritant medicine hydrocortisone with chamomile, aloe and murumuru butter to treat dry, red, irritated localized patches of the skin. Also helps repair and strengthen the skin's natural barrier to prevent future flare-ups.

Developed by Stanford trained Dermatologists Dr. Katie Rodan and Dr. Kathy Fields.

RODAN+FIELDS
DERMATOLOGISTS

30 mL/1 Fl.Oz.

[visit rodanandfields.com](http://visit.rodanandfields.com)

Manufactured for Rodan & Fields, LLC
111 Maiden Lane, Suite 400
San Francisco, CA 94108
Made in the USA SOAN030
8000-06-0001-0A Please Recycle

QUESTIONS OR COMMENTS
1-888-995-5656



8000-06-0001-0A

Dermatologist Developed as needed

Hydrocortisone Lotion

30 mL/ 1 Fl. Oz.

RODAN+FIELDS
SOOTHE

As Needed
Hydrocortisone Lotion

PURPOSE: For temporary relief of itching associated with minor skin irritations. Other uses of this product should be only under the advice and supervision of a doctor.

DIRECTIONS: Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 2 years of age: Do not use, consult a doctor.

ACTIVE INGREDIENTS: Hydrocortisone 1%

WARNINGS: For external use only. Avoid contact with eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor. Do not use in the treatment of diaper rash. Consult a doctor. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

Manufactured for Rodan & Fields, LLC 111 Maiden Lane, Suite 400 San Francisco, CA 94108 Made in USA
8500-06-0001-0A Please Recycle [visit rodanandfields.com](http://visit.rodanandfields.com)
QUESTIONS OR COMMENTS 1-888-995-5656

SOOTHE RODAN FIELDS

hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-2003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SAW PALMETTO (UNII: J7WWH9M8QS)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CETETH-20 (UNII: I835H2IHHX)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
N-ACETYLGLUCOSAMINE (UNII: V956696549)	
TREHALOSE (UNII: B8WCK70T7I)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-2003-2	1 in 1 BOX		
1	NDC:14222-2003-1	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/07/2011	

Labeler - Rodan & Fields, LLC. (051659584)**Registrant** - Cosmetic Enterprises Ltd (017701475)**Establishment**

Name	Address	ID/FEI	Business Operations
Cosmetic Enterprises Ltd		017701475	manufacture

Revised: 1/2012

Rodan & Fields, LLC.