

SKIN LIGHTENING RODAN FIELDS- hydroquinone liquid

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 Reverse 2 Skin Toner

Hydroquinone 2%

Skin Lightening

Keep out of reach of children

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

avoid contact with eyes.

some user of this product may experience a mild skin irritation. if skin irritation becomes severe , stop use and consult a physician.

do not use if pregnant or nursing.

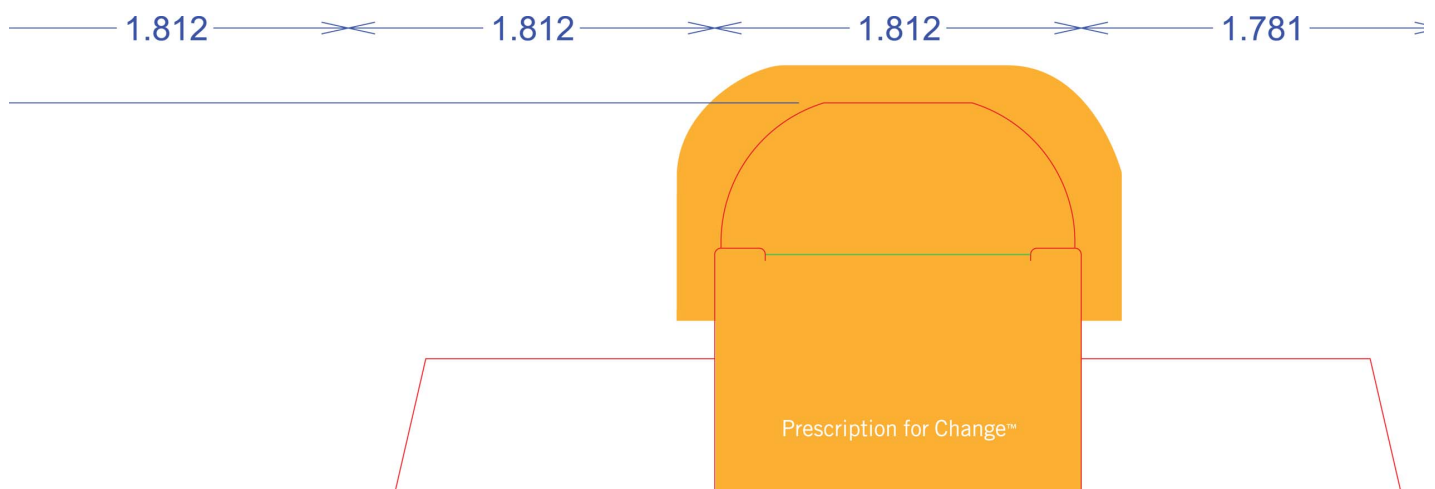
do not use on children under 12 years of age unless directed by a physician.

apply evenly to the entire face with a fresh gauze pad, avoiding the eye area. do not rinse off, allow to dry. use once daily and increase to twice daily as tolerated.

Adult: apply a small amount as a thin layer in affected area once or twice daily, or use as directed by a physician . if no improvement is seen after three months of treatment, use of this product should be discontinued . lightening effect of this product may not be noticeable when used on very dark skin.

children under 12 years of age: do not use unless directed by a physician.

Water (aqua), Ethoxydiglycol, Hamamelis Virgiana (Witch Hazel) Water, Methylpropanediol, Alcohol Denat, Polysorbate 20, Butylene Glycol, Aminopropyl Ascorbyl Phosphate, Foeniculum Vulgare (Fennel) Seed Extract, Magnesium Ascorbyl Phosphate, Arctostaphylos Uva Ursi (leaf) Extract, PEG-12, Dimethicone, Arnica Montana Flower Extract, Zinc Phenolsulfonate, Kojic Acid, Citrus Medica Limonum (Lemon) Peel Extract, Sodium Salicylate, Citric Acid, Sodium Sulfite, Sodium Metabisulfite, DMDM Hydantoin, Fragrance, Yellow 5, Yellow 6



Drug Facts

Active ingredient	Purpose
Hydroquinone 2%	Skin lightener

Uses

For the gradual fading of dark areas such as freckles, age and liver spots, or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.

Warnings

For external use only.

When using this product

- Avoid contact with eyes.
- Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a physician.
- Do not use if pregnant or nursing.
- Do not use on children under 12 years of age unless directed by a physician.

Keep out of reach of children.

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

Directions

- Apply evenly to the entire face with a fresh gauze pad, avoiding the eye area. Do not rinse off. Allow to dry. Use once daily and increase to twice daily as tolerated.
- Adults: apply a small amount as a thin layer on affected area once or twice daily, or use as directed by a physician. If no improvement is seen after three months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin.
- Children under 12 years of age: do not use unless directed by a physician.

Other information

You may report a serious adverse reaction to Rodan+Fields®, Attn: Product Development, ▶

Drug Facts (continued)

111 Maiden Lane, Suite 400, San Francisco, CA 94108.

Inactive ingredients

Water, Ethoxydiglycol, Hamamelis Virgiana (Witch Hazel) Water, Methylpropanediol, Alcohol Denat, Polysorbate 20, Butylene Glycol, Aminopropyl Ascorbyl Phosphate, Foeniculum Vulgare (Fennel) Seed Extract, Magnesium Ascorbyl Phosphate, Arctostaphylos Uva Ursi (Leaf) Extract, PEG-12, Dimethicone, Arnica Montana Flower Extract, Zinc Phenolsulfonate, Kojic Acid, Citrus Medica Limonum (Lemon) Peel Extract, Sodium Salicylate, Citric Acid, Sodium Sulfite, Sodium Metabisulfite, DMDM Hydantoin, Fragrance, Yellow 5, Yellow 6

RODAN+FIELDS®
REVERSE
2 Dermatologist
 Developed
 Skin Lightening
 Toner

RODAN+FIELDS®
DERMATOLOGISTS

125 mL/4.2 Fl.Oz.

Step 2 in the REVERSE Regimen for brown spots, dullness, and sun damage. Proprietary combination of hydroquinone, kojic acid and anti-oxidants brightens skin, evens skin tone and fades brown spots. Salicylic acid and vitamin C help renew and refresh skin for a more radiant complexion. Prepares skin for treatment that follows. Use as part of the REVERSE Regimen for best results.

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

[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 RVTN125 8000-05-0003-0A
 Please Recycle

QUESTIONS OR COMMENTS
1-888-995-5656



for external use only

Rodan and Fields

Reverse

Dermatologist developed skin lightening toner

125 mL/ 4.2 Fl. Oz.



PURPOSE: To lighten and fade brown spots and even skin tone. Prepares skin for Step 3 of the REVERSE Regimen.

DIRECTIONS: Apply evenly to the entire face with a fresh gauze pad, avoiding the eye area. Do not rinse off. Allow to dry. Use once daily and increase to twice daily as tolerated. Adults; apply a small amount as a thin layer on affected area once or twice daily, or use as directed by a physician. If no improvement is seen after three months of treatment, use of this product should be discontinued. Lightening effect of this product may not be noticeable when used on very dark skin. Children under 12 years of age: do not use unless directed by a physician.

ACTIVE INGREDIENT: Hydroquinone 2% - Skin lightener

WARNINGS: For external use only. Avoid contact with eyes. Some users of this product may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a physician. Do not use on children under 12 years of age unless directed by a physician. Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Manufactured for Rodan & Fields, LLC
 111 Maiden Lane, Suite 400 San Francisco, CA 94108
 Made in USA 8500-05-0003-0A Please Recycle
 visit rodanandfields.com

QUESTIONS OR COMMENTS 1-888-995-5656

125 mL/4.2 Fl.Oz.

SKIN LIGHTENING RODAN FIELDS			
hydroquinone liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14222-16 15
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)		HYDROQUINONE	2 mL in 100 mL
Inactive Ingredients			
Ingredient Name			Strength
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118 X02B)			
WITCH HAZEL (UNII: 10 114J0 U34)			
METHYLPROPANEDIOL (UNII: N8 F53B3R4R)			

POLYSORBATE 20 (UNII: 7T1F30V5YH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
FENNEL SEED (UNII: G3QC02NIE6)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
ARCTOSTAPHYLOS UVA-URSILEAF (UNII: 3M5V3D1X36)
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)
DIMETHICONE (UNII: 92RU3N3Y1O)
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)
ZINC PHENOLSULFONATE (UNII: 4O71YT5YB5)
KOJIC ACID (UNII: 6K23F1TT52)
LEMON PEEL (UNII: 72O054U628)
SODIUM SALICYLATE (UNII: WIQ1H85SYP)
SODIUM SULFITE (UNII: VTK01UQK3G)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
DMDM HYDANTOIN (UNII: BYR0546TOW)
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14222-16 15-2	1 in 1 BOX		
1	NDC:14222-16 15-1	125 mL in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	06/06/2011	

Labeler - Rodan & Fields, LLC. (051659584)

Registrant - Cosmetic Enterprises Ltd (017701475)

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