

REFUGE HC - hydrocortisone cream
CoValence 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.

Drug Facts

Active Ingredient(s): Hydrocortisone 1%

Purpose: For itchy skin.

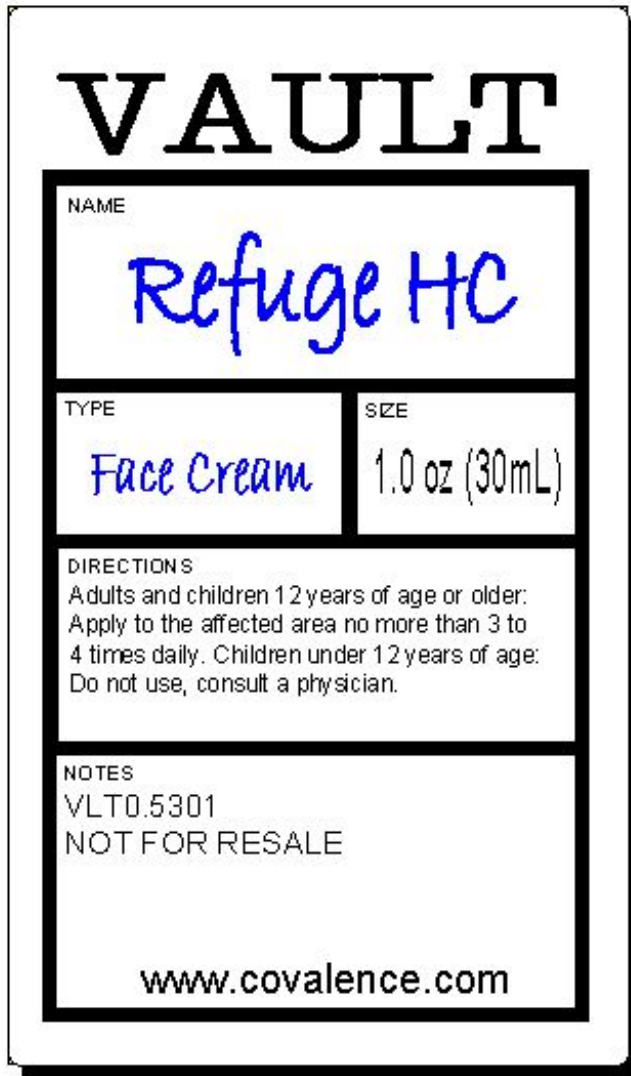
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Children under 12 years of age: do not use, consult a physician.

Use: For temporary relief of itching and discomfort associated with minor skin irritations, inflammation and rashes.

Warnings: For external use only. Avoid contact with eyes.

Directions: Adults and children 12 years of age or older: Apply to the affected area no more than 3 to 4 times daily.

Inactive Ingredients: Aqua (Water), Glycerin, Caprylic/Capric Triglyceride, Cetearyl Oliviate, Hedychium Coronarium (White Ginger) Root Extract, Bisabolol (L-alpha), Rosa Canina (Rose Hip) Fruit Oil, Squalane, Tocopherol (D-alpha), Aloe Barbadensis Leaf Juice Powder, Lonicera Caprifolium (Honeysuckle) Flower Extract, Lonicera Japonica (Honeysuckle) Flower Extract, Glycine Soja (Soybean) Oil, Sorbitan Oliviate, Xanthan Gum, Phytic Acid, Carbomer, Potassium Sorbate, Sodium Hydroxide, Calcium Gluconate, Gluconolactone, Sodium Benzoate, Caprylyl Glycol, Phenethyl Alcohol, Trisodium Ethylenediamine Disuccinate



Principal Display Panel

REFUGE HC

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66915-531
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	.01 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

CETEARYL OLIVATE (UNII: 58B69Q84JO)
HEDYCHUM CORONARIUM ROOT (UNII: 92A6N0IQN9)
LEVOMENOL (UNII: 24WE03BX2T)
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)
SQUALANE (UNII: GW89575KF9)
TOCOPHEROL (UNII: R0ZB2556P8)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
SOYBEAN OIL (UNII: 241ATL177A)
SORBITAN OLIVATE (UNII: MDL271E3GR)
XANTHAN GUM (UNII: TTV12P4NEE)
PHYTIC ACID (UNII: 7IGF0S7R8I)
CARBOMER 934 (UNII: Z135WT9208)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
GLUCONOLACTONE (UNII: WQ29KQ9POT)
SODIUM BENZOATE (UNII: OJ245FE5EU)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66915-531-01	30 g in 1 JAR		
2	NDC:66915-531-02	200000 g in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/02/2011	

Labeler - CoValence Inc. (070659375)

Establishment

Name	Address	ID/FEI	Business Operations
CoValence Inc.		070659375	manufacture