

GLO SKIN BEAUTY REMEDY GEL- glo skin beauty remedy gel gel

Hayden Caleel 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.

DRUG FACTS

Active Ingredients

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to:
- dermatitis, eczema, insect bites
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- for the treatment of diaper rash. Ask a doctor

When using this product

- avoid contact with the eyes
- do not use more than directed unless told to do so by a doctor

Stop use and ask a doctor if

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

Keep out of reach of children

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

Directions

- for itching of skin irritation, inflammation and rashes
- 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, ask a doctor

Inactive Ingredients

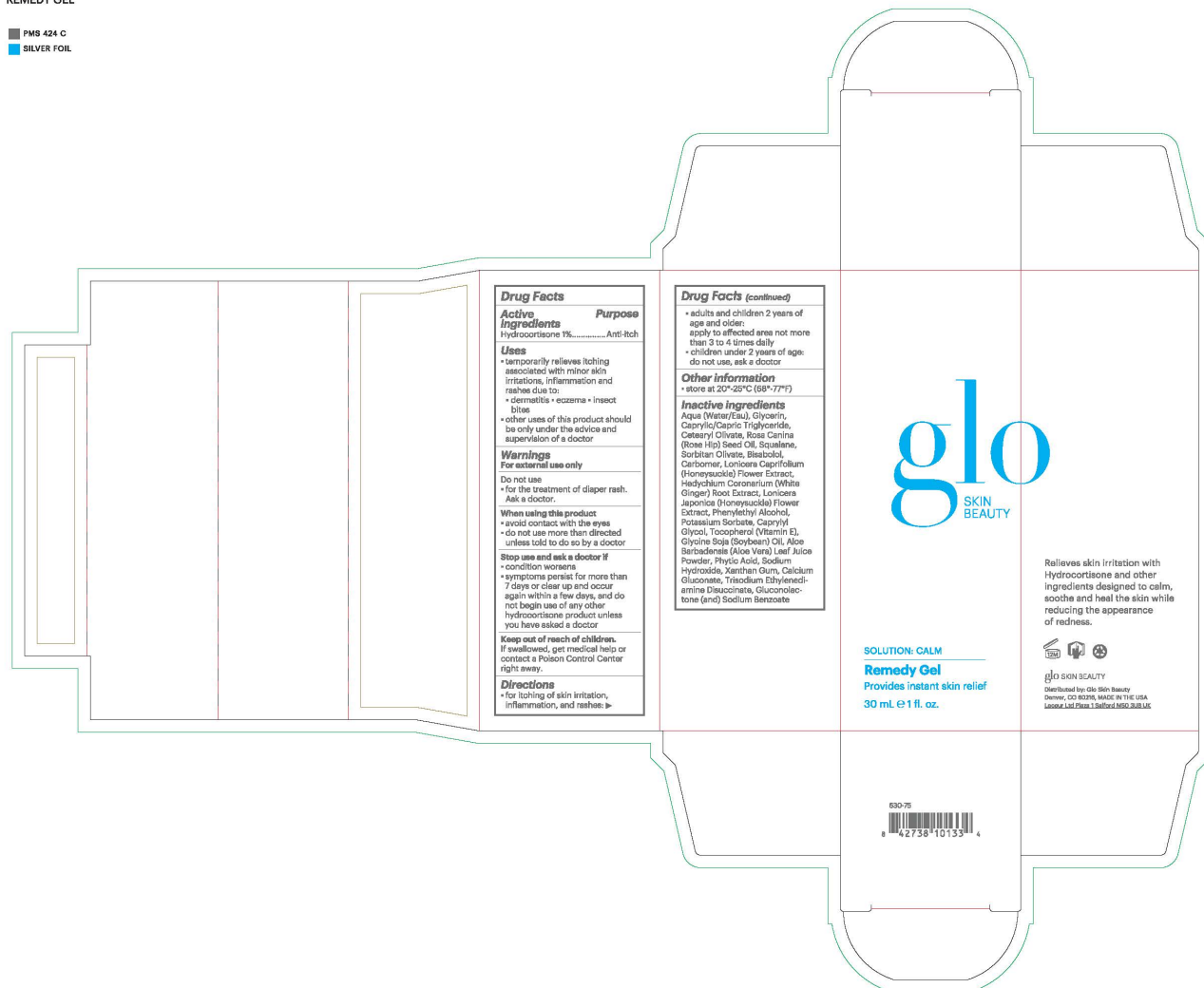
Aqua (Water), Glycerin, Caprylic/Capric Triglyceride, Cetearyl Oliviate, Rosa Canina (Rose Hip) Fruit Oil, Squalane, Sorbitan Oliviate, Bisabolol, Carbomer, Gluconolactone, Lonicera Caprifolium (Honeysuckle) Flower Extract, Hedychium Coronarium (White Ginger) Root Extract, Lonicera Japonica

(Honeysuckle) Flower Extract, Sodium Benzoate, Phenethyl Alcohol, Potassium Sorbate, Caprylyl Glycol, Tocopherol, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice Powder, Phytic Acid, Sodium Hydroxide, Xanthan Gum, Trisodium Ethylenediamine Disuccinate

Principal Display Panel

REMEDY GEL

■ PMS 424 C
■ SILVER FOIL



GLO SKIN BEAUTY REMEDY GEL			
glo skin beauty remedy gel gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60541-1900
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)		HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
SQUALANE (UNII: GW89575KF9)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GLUCONOLACTONE (UNII: WQ29KQ9POT)	
LONICERA CAPRIFOLIUM FLOWER (UNII: 5N1WD9784U)	
HEDYCHUM CORONARIUM ROOT (UNII: 92A6N0IQN9)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SOYBEAN OIL (UNII: 241ATL177A)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
SODIUM HYDRIDE (UNII: 23J3BHR95O)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60541-1900-3	1 in 1 CARTON	12/31/2017	
1		30 g in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/31/2017	

Labeler - Hayden Caleel LLC (011367468)

Registrant - Hayden Caleel LLC (011367468)

Establishment

Name	Address	ID/FEI	Business Operations
Island Kinetics, Inc. d.b.a. Co Valence Laboratories		959735002	manufacture(60541-1900)