SUMMERS EVE ACTIVE CHAFE- dimethicone gel C.B. Fleet Company, 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.

Summers Eve Active Chafe Gel

Drug Facts

Active Ingredient

Purpose

Dimethicone 1.2%.....Skin Protectant

Use

Temporarily protects and helps relieve chafed, chapped, or cracked skin

Warnings

For external use only.

Do not use on

- deep or puncture wounds
- animal bites
- serious burns

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms lasts more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Apply as needed.

Other information

Store at 20° - 25°C (68°-77°F)

Inactive Ingredients

dimethicone, dimethicone/vinyl dimethicone crosspolymer, cyclopentasiloxane, vinyl dimethicone/methicone silsesquioxane crosspolymer, silica dimethyl silylate

Questions?

866 - 787 - 6383 or Summerseve.com

PRINCIPAL DISPLAY PANEL

Summer's Eve Active Chafe Gel Dimethicone 1.2%/Skin Protectant Net Wt. 1.5 oz (42g)



SUMMERS EVE ACTIVE CHAFE

dimethicone gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0132-8744

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	12 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)			
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)			
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)			

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging					
#	tem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:0132-8744- 42	1 in 1 CARTON	01/12/2021			
1		42 g in 1 JAR; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part347	01/12/2021			

Labeler - C.B. Fleet Company, Inc. (003119054)

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