

PREQUEL- multi purpose skin protectant ointment
The Center Brands, 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

Purpose

Skin Protectant

Active Ingredients

Petrolatum 45.00%

Uses

- Temporarily protects and helps relieve chafed, chapped or craked skin and lips
- Temporarily protects minor:
 - cuts
 - scrapes
 - burns
- Helps protect form the drying effects of wind and cold weather

Warnings

Fox external use only.

When using this product do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days. Do not use on • deep or puncture woulds • animal bites • serious burns.

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

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Directions

Apply as needed.

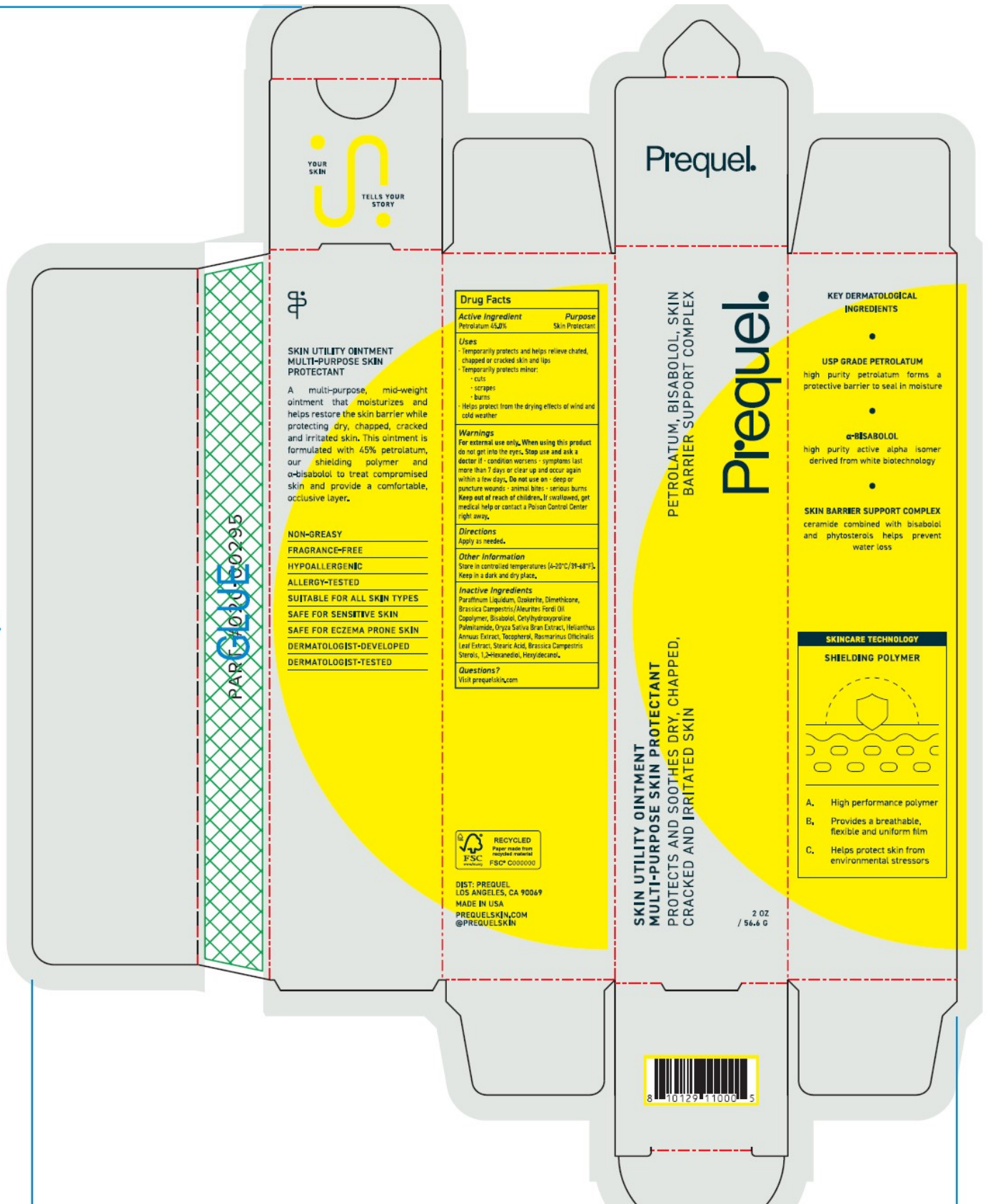
Inactive Ingredients

Paraffinum Liquidum, Ozokerite, Dimethicone, Brassica Campestris/Aleuites Fordi Oil Copolymer, Bisabolol, Cetylhydroxyproline Palmitamide, Oryza Sativa Bran Extract, Helianthus Annuus Extract, Tocopherol, Rosmarinus Officinalis Leaf Extract, Stearic Acid, Brassica Campestris Sterols, 1,2-Hexanediol, Hexyldecanol

Other Information

Visit prequelskin.com

Principal Display Panel



PREQUEL
 multi purpose skin protectant ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82800-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	45 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HEXYLDECANOL (UNII: 151Z7P1317)	
CERESIN (UNII: Q1LS2UJO3A)	
RAPESEED STEROL (UNII: B46B6DD20U)	
ROSEMARY (UNII: IJ67X351P9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
TOCOPHEROL (UNII: R0ZB2556P8)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)	
LEVOMENOL (UNII: 24WE03BX2T)	
CETYLHYDROXYPROLINE PALMITAMIDE (UNII: 74ONU0S62G)	
RICE BRAN (UNII: R60QEP13IC)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82800-008-01	1 in 1 BOX	07/13/2023	
1		56.6 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M016	07/13/2023	

