

**PREQUEL SKIN UTILITY BALM MULTI-PURPOSE SKIN PROTECTANT- skin
protectant balm ointment
The Center Brands, LLC**

DRUG FACTS

Purpose

Skin Protectant

Active Ingredients

Dimethicone 5.25%

Uses

Temporarily protects and helps relieve chafed, chapper or cracked skin
Helps protect fomr 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

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

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Directions

Apply as needed.

Inactive ingredients

Water (Aqua), Propanediol, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter,
Undecane, Glycerin, Dipentaerythryityl Hexahydrostearate/Hexastearate/Hexarosinate,
Isosorbate Dicaprylate, Cetearyl Oliviate, Tridecane, Sorbitan Oliviate, Silica, Ceramide NP,
Cholesterol, Phytospingosine, Hydrogentaed Lecithin, Centella Asiatica Extract, Sodium
Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Ammonium
Acryloyldimethyltuarate/VP Copolymer, Hydrogenated Polydecene, Xanthan Gum, Stearic

Acid, Sodium Phytate, Tocopheryl Acetate, Camomilla Recutita Flower Extract, Aloe Barbadensis Leaf Juice, Phenoxyethanol, Ethylhexylglycerin, Citric Acid, Caprylic/Capric Triglyceride, Lactic Acid, Oleic Acid, Laureth-8, Caprylyl Glycol, Caprylhydroxamic Acid, Tocopherol, Potassium Sorbate, Sodium Benzoate, Sodium Sulfate, t-Butyl Alcohol

Other Information

- Store in controlled temperatures (4-20°C/39-68°F). Keep in a dark and dry place.

Questions?

Visit prequelskin.com

Principal Display Panel

PREQUEL SKIN UTILITY BALM MULTI-PURPOSE SKIN PROTECTANT

skin protectant balm ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82800-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	5.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
UNDECANE (UNII: JV0QT00NUE)	
DIPENTAERYTHRITYL HEXASTEARATE (UNII: WTF09990PK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOSORBIDE DICAPRYLATE (UNII: 0IK29C4889)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CERAMIDE NP (UNII: 4370DF050B)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
LACTIC ACID (UNII: 33X04XA5AT)	
OLEIC ACID (UNII: 2UMI9U37CP)	
LAURETH-8 (UNII: QU7U88D04I)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
TOCOPHEROL (UNII: R0ZB2556P8)	

POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SULFATE (UNII: 0YPR65R21J)	
TERT-BUTYL ACETATE (UNII: 76N22HKP3X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82800-060-01	1 in 1 PACKAGE	10/30/2023	
1		50 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 Drug	M016	10/30/2023	

Labeler - The Center Brands, LLC (076228814)

Revised: 12/2024

The Center Brands, LLC