

BARRIER CREAM- zinc oxide cream
Avasol LLC

Barrier Cream

Active Ingredients

Zinc Oxide (Non-nano) 10%

Purpose

Skin protectant

Uses

- Temporarily protects the skin and prevents chafing, blisters and irritation and helps seal out wetness.
- Helps prevent and helps relieve minor skin irritation and itching due to rashes, chafed, chapped, cracked, or windburned skin.

Warnings

- **For external use only**
- **Avoid contact with eyes. Rinse with water to remove.**

Stop use and ask a doctor

- Condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

Do not use:

- if allergic to ingredients.
- on deep or puncture wounds
- on animal bites •on serious burns.
- Test small area first.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply liberally, directly on skin as needed. Safe to apply to prosthetics, protective equipment, etc.

Inactive ingredients

*Caprylic/Capric Triglyceride (Fractionated Coconut Oil), *Cocos Nucifera (Coconut) Oil,

*Cera Alba (beeswax), **Euphorbia Cerifera (candelilla) wax, *Simmondsia Chinensis (Jojoba) Seed Oil, Tocopherol, Olea Europaea (Olive) Leaf Extract, Citrus Aurantium Dulcis Peel Cera, Astaxanthin, Bentonite, Cetearyl Olivat, Sorbitan Olivat, *Propolis, *Lavandula Angustifolia (Lavender) Oil, *Rosmarinus Officinalis (Rosemary) Leaf Extract,*Aloe barbadensis,*St. John's wort (Hypericum perforatum),*Chamomile (Matricaria chamomilla L), *Licorice Root (Glycyrrhiza glabra), *Calendula Officinalis Flower Extract, **Leptospermum scoparium (Manuka) Oil, *Mentha Piperita (Peppermint) Oil *Organic

Other information

store product between 45 to 100F

Gently warm or knead product as needed to soften before use.

Questions?

Call **888-805-1507** or visit **www.avasol.com**



BARRIER CREAM

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58518-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	100 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
COCONUT OIL (UNII: Q9L0O73W7L)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
ORANGE PEEL WAX (UNII: 0U715N387C)	
ASTAXANTHIN (UNII: 8XPW32PR7I)	
BENTONITE (UNII: A3N5ZCN45C)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ROSEMARY (UNII: IJ67X351P9)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
ST. JOHN'S WORT (UNII: UFH8805FKA)	
CHAMOMILE (UNII: FGL3685T2X)	
LICORICE (UNII: 61ZBX54883)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
PEPPERMINT OIL (UNII: AV092KU4JH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58518-040-02	59 mL in 1 POUCH; Type 0: Not a Combination Product	01/01/2022	
2	NDC:58518-040-03	28 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	01/01/2022	

Labeler - Avasol LLC (078822898)

Establishment

Name	Address	ID/FEI	Business Operations
Avasol LLC		078822898	manufacture(58518-040)

Revised: 5/2023

Avasol LLC