

BARRIER CREAM- zinc oxide cream
Avasol 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

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. May be applied to prosthetics, protective equipment, etc. Will solidify at cold temps. Warm and knead as required.

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 Oliviate, Sorbitan Oliviate, *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 **Wildcrafted**

Other information

Protect from freezing. Avoid excessive heat.

Questions?

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

Principal Display Panel - 59 mL Pouch Label

avasol®

**BARRIER
CREAM**

BIOBASED

Multipurpose

Anti-chafing

Skin protectant

No Petrochemicals • No Synthetics

2 FL OZ (59 mL)



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 not final	part352	01/01/2022	

Labeler - Avasol LLC (078822898)

Establishment

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

Revised: 4/2023

Avasol LLC