

HEALING- petrolatum ointment
Topco Associates 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.

Healing Ointment for Dry and Cracked Skin
247.000/247AA-AC

Active ingredient

Petrolatum 41%

Purpose

Skin protectant (ointment)

Uses

- temporarily protects minor: cuts, scrapes, burns
- temporarily protects and helps relieve chapped or cracked skin and lips
- helps protect from the drying effects of wind and cold weather

Warnings

For external use only

When using this product

- do not get in 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 wounds
- animal bites
- serious burns

Keep out of reach of children

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

Directions

- apply as needed

Inactive ingredients

mineral oil, ceresin, lanolin alcohol, panthenol, glycerin, bisabolol

Questions?

Call 1-888-423-0139

Claims

TopCARE beauty

For dry, cracked or irritated skin

Restores smooth, healthy skin

Fragrance-free - Hypoallergenic

Dermatologist tested

*This product is not manufactured or distributed by Beiersdorf, Inc., distributor of Aquaphor Healing Ointment.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

(C) TOPCO VIJS0220 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

principal display panel

TopCare

beauty

ADVANCED

HEALING OINTMENT

SKIN PROTECTANT

Compare to Aquaphor*

For dry & cracked skin

Fragrance Free

NET WT 14 OZ (396 g)



ADVANCED HEALING OINTMENT

SKIN PROTECTANT

Compare to Aquaphor®*

For dry & cracked skin

Fragrance
Free

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14 OZ (396 g)

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HEALING

petrolatum ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-247
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	410 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
CERESIN (UNII: Q1LS2UJO3A)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	
PANTHENOL (UNII: WV9CM0O67Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
LEVOMENOL (UNII: 24WE03BX2T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:36800-247-41	396 g in 1 JAR; Type 0: Not a Combination Product	11/01/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part347		11/01/2013	

Labeler - Topco Associates LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-247)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-247)