

CONCEALING SPOT TREATMENT- sulfur lotion

Dermologica, Inc.

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.

Concealing Spot Treatment

Drug Facts

Active ingredient

Sulfur (5.0%)

Purpose

Acne treatment

Indications

- For the treatment of acne.

Warnings

For external use only

Do not use

- on broken skin.
- on large areas of the body.

Using other topical acne medications

- at the same time or immediately following use of this product may increase dryness or or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Stop use and ask a doctor

- if excessive skin irritation develops or increases.

Keep out of reach of children

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

Directions

- Dot onto finger and apply to cleansed skin.
- Let stand for five seconds, then pat until blended in.
- Use 1-2 times daily until breakout has cleared.

Inactive ingredients

Hamamelis Virginiana (Witch Hazel) Water, Ethyl Trisiloxane, Butylene Glycol, Silica Dimethyl Silylate, Cetearyl Alcohol, Peg-40 Hydrogenated Castor Oil, Dimethicone, Ceratonia Siliqua (Carob) Seed Extract, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Cinnamomum Zeylanicum Bark Extract, Niacinamide, Yeast Extract, Salicylic Acid, Biotin, Zinc Gluconate, Panthenol, Montmorillonite, Caffeine, Lauryl PEG/PPG-18/18 Methicone, Camphor, Capryloyl Glycine, Sarcosine, Ammonium

Glycyrrhizate, Cetareth-20, Potassium Alum, Water, Xanthan Gum, Ethylhexylglycerin, Phenoxyethanol, Iron Oxides (CI 77492), (CI 77491), (CI 77499), Titanium Dioxide (CI 77891), Zinc Oxide (CI 77947).

Questions or comments?

Call toll free **1-800-831-5150** in the US

PRINCIPAL DISPLAY PANEL - 10 mL Tube Carton

new

improved

formula

concealing

spot

treatment

acne treatment

mediBac clearing[®]

0.33 US FL OZ

10 mL e

dermalogica[®]

concealing spot treatment

Tinted spot treatment ideal for daytime coverage of breakouts. Conceals and helps clear breakouts upon contact. Sulfur helps eliminate breakout-causing bacteria while clearing excess oil and congestion in the follicle. Biotin helps purify and inhibit overactive oil production while Carob Seed Extract helps accelerate skin recovery. Witch Hazel and Camphor help purify and soothe the skin.

Formulated without artificial fragrances, colors or parabens. Product guaranteed when professionally recommended.



Made in the USA

© Dermalogica, Inc.
Dermalogica, Dist.
Los Angeles, CA 90009 USA
1-800-831-5150
Europe: London KT22 8JB UK

dermalogica
dermalogica.com

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concealing spot treatment

new improved formula

concealing spot treatment

acne treatment
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a skin care system researched and developed by The International Dermal Institute

Drug Facts (continued)

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(D1325-00)

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CONCEALING SPOT TREATMENT

sulfur lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68479-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
ETHYL TRISILOXANE (UNII: ZH1WJO5481)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
NIACINAMIDE (UNII: 25X51I8RD4)	
YEAST, UNSPECIFIED (UNII: 3NY3SM6B8U)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
BIOTIN (UNII: 6SO6U10H04)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
PANTHENOL (UNII: WV9CM0O67Z)	
MONTMORILLONITE (UNII: A585MN1H2L)	
CAFFEINE (UNII: 3G6A5W338E)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
SARCOSINE (UNII: Z711V88R5F)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
POTASSIUM ALUM (UNII: 1L24V9R23S)	
WATER (UNII: 059QF0K00R)	

XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68479-005-02	1 in 1 CARTON		
1		10 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68479-005-01	3 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68479-005-00	2 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	04/22/2014	

Labeler - Dermalogica, Inc. (177698560)

Establishment

Name	Address	ID/FEI	Business Operations
PakLab		790530976	MANUFACTURE(68479-005)

Establishment

Name	Address	ID/FEI	Business Operations
Diamond Wipes		161104729	MANUFACTURE(68479-005)