DERMAHARMONY 10% SULFUR WITH TEA TREE OIL- sulfur soap
D3 Development, 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.

Dermaharmony 10% Sulfur Soap with Tea Tree Oil

Drug Facts

Active ingredient

Sulfur 10%

Purpose

Acne medication soap

Uses

- For the treatment of acne.
- Clears acne blemishes, blackheads, and whiteheads.

Warnings

For external use only

Do not use on

- broken skin.
- large areas of the skin.

When using this product

- apply only to areas with acne.
- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

Stop use and ask a doctor if skin irritation occurs or gets worse.

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

Directions

- using warm water, wash affected area for 1-2 minutes, avoiding contact with the eyes.
- rinse thoroughly and pat dry with a clean towel.
- because excessive drying of the skin may occur start with 1 application daily, then gradually increase to 2-3 times daily if needed or as directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Other information Store at room temperature in a dry place.

Inactive ingredients

Sodium palmate, sodium cocoate*, sodium palm kernelate*, water, glycerin, tea tree (Melaleuca alternifolia) oil, sodium chloride, coconut (Cocos nucifera) fruit extract, palm (Elaeis guineensis) fruit extract, pentasodium penetate

*May contain this ingredient

Questions?

1-800-827-3730 www.dermaharmony.com

Distributed by: D3 Development, Inc., Portland, ME 04101

Made in USA

dermaharmony

10% Sulfur SOAP with Tea Tree Oil

For Acne Pimples, Blackheads & Whiteheads

NET WT 4 OZ (113 G)

Drug Facts (continued)

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10% Sulfur

DERMAHARMONY 10% SULFUR WITH TEA TREE OIL

sulfur soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71819-015
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
ELAEIS GUINEENSIS FRUIT (UNII: 80T6U6714J)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
SODIUM COCOATE (UNII: R1TQH25F4I)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	
COCONUT (UNII: 3RT3536DHY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71819-015-04	113 g in 1 POUCH; Type 0: Not a Combination Product	07/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	07/20/2021	

Labeler - D3 Development, Inc. (043195877)

Revised: 7/2021 D3 Development, Inc.