

DERMAHARMONY TEA TREE BAR- pyrithione zinc shampoo
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 Tea Tree Shampoo Bar

Drug Facts

Active ingredient

Pyrithione zinc 2%

Purpose

Dandruff / seborrheic dermatitis shampoo

Uses

Controls and reduces the symptoms of dandruff and seborrheic dermatitis.

Warnings

For external use only

Ask a doctor before use if you have a condition that covers a large area of the body.

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.

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

Directions

- Use on affected areas in place of your regular shampoo
- For best results use at least twice a week or as directed by a doctor
- Rub between hands to create a lather, or apply bar directly onto hair
- Massage into the hair and scalp for 60-90 seconds, then rinse well

Other information

- Store at room temperature

Inactive ingredients

Sodium cocoyl isethionate (SCI), stearic acid, coconut fatty acid, sodium isethionate, tea tree (*Melaleuca Alternifolia*) leaf oil, water, soyethyl morpholinium ethosulfate, coco glucoside, cetearyl alcohol & cetareth-20, benzyl alcohol, dehydroacetic acid, oat (*Avena Sativa*) flour, sodium methyl 2 sulfolaurate & disodium 2-sulfolaurate, argan oil, sucrose cocoate, sodium isostearoyl lactylate, iron oxides (ochre).

Questions?

1-800-827-3730

www.dermaharmony.com

Distributed by:

D3 Development, Inc., Portland, ME 04101

Made in USA of U.S. and imported ingredients.

NDC Code: 71819-018-04

dermaharmony

**TEA TREE Shampoo Bar
with 2% Pyrithione Zinc
FOR DANDRUFF & SEBORRHEIC DERMATITIS
NET WT 4 OZ (113G)**



DERMAHARMONY TEA TREE BAR

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71819-018
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
OATMEAL (UNII: 8PI54V663Y)	
TEA TREE OIL (UNII: VIF565UC2G)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
ARGAN OIL (UNII: 4V59G5UW9X)	
DISODIUM 2-SULFOLAURATE (UNII: 329M3829G2)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
COCO GLUCOSIDE (UNII: ICS790225B)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
COCONUT ACID (UNII: 40U37V505D)	
SOYETHYL MORPHOLINIUM ETHOSULFATE (UNII: J8C5W5HH18)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM METHYL 2-SULFOLAURATE (UNII: I39GGJ23HV)	
SODIUM ISETHIONATE (UNII: 3R36J71C17)	
SUCROSE COCOATE (UNII: 3H18P0UK73)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71819-018-04	113 g in 1 CARTON; Type 0: Not a Combination Product	09/29/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M032	09/29/2022	

Labeler - D3 Development, Inc. (043195877)

Revised: 9/2022

D3 Development, Inc.