PYRITHIONE ZINC- pyrithione zinc shampoo OLD EAST MAIN CO.

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.

Tea Tree 2 in 1 Dandruff Shampoo and Conditioner 470AB/470.000

claims

Multiple Benefit formula to help:

- Fight dry scalp
- Calm itch
- Relieve irritation
- Soothe and reduce redness
- Reduce oiliness
- Prevent flakes
- Leave hair healthy looking

Active ingredient

Pyrithione Zinc 1%

Purpose

Anti-dandruff

Use

helps prevent recurrence of flaking and itching associated with dandruff

Warnings

For external use only

When using this product

• do not get into 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

- shake well
- for maximum dandruff controll, use every time you shampoo
- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor

inactive ingredients

water, sodium lauryl sulfate, sodium laureth sulfate, glycol distearate, sodium chloride, zinc carbonate, sodium xylenesulfonate, amodimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, magnesium carbonate hydroxide, Mentha piperita (peppermint) oil, Mentha arvensis leaf oil, Melaleuca alternifolia (tea tree) leaf oil, citric acid, methylchloroisothiazolinone, methylisothiazolinone, hydroxycitronellal, linalool, blue 1, yellow 5

Disclaimer

*This product is not manufactured or distributed by Procter & Gamble, the distributor of Head & Shoulders $^{\circledR}$ Tea Tree Oil 2in1 Dandruff Shampoo + Conditioner.

Adverse Reactions

100% Satisfaction

Guaranteed!

(888)309-9030

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Principal display panel

STUDIO

SELECTION

TEA TREE

DANDRUFF SHAMPOO + CONDITIONER

PYRITHIONE ZINC 1%

Compare to Head & Shoulders® Tea Tree Oil 2 in 1 Dandruff Shampoo & Conditioner*

Cooling relief from scalp itch

Paraben free

2in1
Paraben + Phthalate Free
12.5 FL OZ (370 mL)



PYRITHIONE ZINC

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75712-470
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:75712- 470-32	370 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/25/2023	

Marketing Information				
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	09/25/2023		

Labeler - OLD EAST MAIN CO. (006946172)

Registrant - Vi-Jon, LLC (790752542)

EstablishmentNameAddressID/FEIBusiness OperationsVi-Jon, LLC790752542manufacture(75712-470)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(75712-470)	

Revised: 9/2023 OLD EAST MAIN CO.