

**CYZONE TRAX COOLTURE DERMO COOL- pyrrithione zinc liquid
VENTURA CORPORATION LTDA.,**

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.

Trax Coolture Antidandruff Shampoo

Drug Facts

Active Ingredient

Pyrrithione zinc 0.5%

Purpose

Antidandruff shampoo

Uses

Reduces the symptoms of dandruff

Warnings

For external use only

Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

If condition worsens or does not improve after regular use of this product as directed, consult a doctor

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

Directions

For best results use at least twice a week or as directed by a doctor.

Inactive ingredients

Aqua (water), sodium laureth sulfate, cocamide dea, cocamidopropyl betaine, dimethiconol, sodium chloride, parfum (fragrance), acrylates/c10-30 alkyl acrylate crosspolymer, glycol distearate, triethanolamine, guar hydroxypropyltrimonium chloride, coco-glucoside, tea-dodecylbenzenesulfonate, citric acid, , glyceryl stearate, , glyceryl oleate, magnesium nitrate, zinc chloride, hydrolyzed wheat protein, tocopheryl acetate, panthenol, menthyl pca, methylchloroisothiazolinone, magnesium chloride, methylisothiazolinone, menthol, dipropylene glycol, saccharomyces/sea salt ferment, ci 42090 (blue 1), ci 17200 (red 33), ci 19140 (yellow 5).

Questions?

Puerto Rico: 622-3235 (San José)

**PRINCIPAL DISPLAY PANEL - 300 ml Bottle Label
SHAMPOO 2 EN 1**

CONTROL CASPA

**trax
coolture**

DERMO COOL

cy°zone

300 ml e
(10.1 fl.oz.)



CYZONE TRAX COOLTURE DERMO COOL

pyrithione zinc liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyrithione zinc (UNII: R953O2RHZ5) (Pyrithione zinc - UNII:R953O2RHZ5)	Pyrithione zinc	15 g in 300 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
sodium laureth sulfate (UNII: BPV390UAP0)	
coco diethanolamide (UNII: 92005F972D)	
cocamidopropyl betaine (UNII: 5OCF3O11KX)	
sodium chloride (UNII: 451W47IQ8X)	
glycol distearate (UNII: 13W7MDN21W)	
trolamine (UNII: 9O3K93S3TK)	
chloride ion (UNII: Q32ZN48698)	
citric acid monohydrate (UNII: 2968PHW8QP)	
glyceryl monostearate (UNII: 230OU9XXE4)	
glyceryl monooleate (UNII: 4PC054V79P)	
magnesium nitrate (UNII: 77CBG3UN78)	
zinc chloride (UNII: 86Q357L16B)	
wheat (UNII: 4J2I0SN84Y)	
alpha-tocopherol acetate (UNII: 9E8X80D2L0)	
panthenol (UNII: WV9CM0O67Z)	
methylchloroisothiazolinone (UNII: DEL7T5QRPN)	
methylisothiazolinone (UNII: 229D0E1QFA)	
magnesium chloride (UNII: 02F3473H9O)	
menthol (UNII: L7T10EIP3A)	
dipropylene glycol (UNII: E107L85C40)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-301-60	300 mL in 1 BOTTLE		
2	NDC:13537-301-70	10 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	08/15/2010	

