OCEAN BREEZE 2 IN 1 DANDRUFF SEA MINERAL SCENT- pyrithione zinc shampoo SUPERVALU 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.

BACK LABEL - DRUG FACTS BOX

ACTIVE INGREDIENT

PYRITHIONE ZINC 1%

PURPOSE

ANTI-DANDRUFF

WARNINGS

FOR EXTERNAL USE ONLY

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE EYES THROUGHLY WITH WATER.

STOP USE AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE AFTER REGULAR USE OF THIS PRODUCT AS DIRECTED

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT POISON CONTROL CENTER IMMEDIATELY.

Uses

HELPS PREVENT RECURRENCE OF FLAKING AND ITCHING ASSOCIATED WITH DANDRUFF

Directions

FOR MAXIMUM DANDRUFF CONTROL, USE EVERY TIME YOU SHAMPOO. WET HAIR, MASSAGE ONTO SCALP AND RINSE. REPEAT IF DESIRE.

Inactive Ingredients

Water (Aqua), Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Cocamide MEA, Zinc Carbonate, Glycol Distearate, Fragrance (Parfum), Dimethicone, Cetyl Alcohol, Polyquaternium-10, Magnesium Sulfate, Sodium Benzoate, Menthol, PEG-7M, Magnesium Carbonate Hydroxide, Ammonium Laureth Sulfate, Sea Salt, Fucus Vesiculosus Extract, Benzyl Alcohol, Sodium Chloride, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Xylene Sulfonate, Blue 1 (CI 42090), Yellow 5 (CI 19140)

PACKAGE FRONT AND BACK LABELS

14OZ Front and Back Labels: eq14.jpg





OCEAN BREEZE 2 IN 1 DANDRUFF SEA MINERAL SCENT

pyrithione zinc shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41163-420	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 mL in 100 mL		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:41163-420-14	420 mL in 1 BOTTLE, PLASTIC				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part358H	07/01/2010			

Labeler - SUPERVALU INC (006961411)

Revised: 7/2010 SUPERVALU INC