

**HEAD AND SHOULDERS REFRESHING RELIEF- head and shoulders lotion/shampoo
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.**

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.

Head and Shoulders Refreshing Relief

Purpose

With refreshing ingredients for immediate sensation

*up to 100% dandruff free

With Regular use, H&S 3action formula cleans, protects and hydrates hair and scalp.

Head and Shoulders Refreshing Relief with balanced PH contains ingredients that in contact with the skin unleash refreshing sensations that immediately reduce the itching related to dandruff

*Visible dandruff, using it often.

Active Ingredient

Active

Ingredient.....	Purpose
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Pyrithione Zinc 1%.....	Anti-dandruff
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Indications:

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 thoroughly with water

Stop use and ask 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 before use - apply in wet hair - massage into scalp - rinse
- repeat as desired
- for best results use at least twice a week or as directed by a doctor
- for maximum dandruff control, use every time you shampoo

Inactive Ingredients

Water, Sodium Laureth Sulfate, Sodium Lauryl Sulfate, Cocamide MEA, Zinc Carbonate, Glycol distearate, sodium xylenesulfonate, Fragrance, Dimethicone, Cetyl Alcohol, Guar Hydroxypropyltrimonium Chloride, Hydrochloric Acid, Magnesium Sulfate, Sodium Chloride, Sodium Benzoate, Magnesium Carbonate Hydroxide, Hexyl Cinnamal, Benzyl Alcohol, Mentha Piperita Oil, Menthol, Mentha arvensis leaf oil, Hydroxycitronellal, Linalool, FD&C Yellow No. 5, Methylisothiazolinone, FD&C Blue No. 1

Distributed by:

ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.

Made in Mexico

HEAD & SHOULDERS

Antidandruff Shampoo REFRESHING RELIEF

Refreshing Relief

Head & Shoulders Antidandruff Shampoo **REFRESHING RELIEF**

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*Up to 100% dandruff free

3 Action Formula™

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and hydrates hair and scalp.

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Drug Facts

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IMAGE III MEXICO

DISTRIBUTED BY:

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12.68 FL. OZ (375 ML)

HEAD AND SHOULDERS REFRESHING RELIEF

head and shoulders lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72389-108
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 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
LINALOOL, (-)- (UNII: 3U21E3V8I2)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE) (UNII: B16G315W7A)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
ZINC CARBONATE (UNII: EQR32Y7H0M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MAGNESIUM SULFATE, UNSPECIFIED (UNII: DE08037SAB)	

MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72389-108-02	375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/27/2018	
2	NDC:72389-108-03	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/27/2018	

Labeler - ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V. (812839648)

Registrant - ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V. (815333653)

Establishment

Name	Address	ID/FEI	Business Operations
PROCTER & GAMBLE MANUFACTURING MEXICO, S. DE R.L. DE C.V.		812807550	manufacture(72389-108)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		812839648	label(72389-108)

Revised: 1/2022

ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.