

**HEAD AND SHOULDERS 2 IN 1 INSTANT MOISTURIZATION- 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.*

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**Head and Shoulders 2 in 1 INSTANT MOISTURIZATION**

**Purpose**

Feel your hair and scalp instantly moisturized

\*Up to 100% dandruff free

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

Head and Shoulders Instant Moisturization with balanced PH contains ingredients that upon contact with the skin create a moisture mesh that help immediately nourish hair and scalp.

Additionally, its formula leaves your hair up to 100% free of dandruff\*

\*Visible dandruff, using it often.

**Active Ingredient**

<b>Active Ingredient.....</b>	<b>Purpose</b>
Pyrithione Zinc 1%.....	Anti-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 our 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, Dimethicone, Cocamide MEA, Zinc Carbonate, Glycol Distearate, Sodium Xylenesulfonate, Cetyl Alcohol, Fragrance, Guar Hydroxypropyltrimonium Chloride, Hydrochloric Acid, Magnesium Sulfate, Sodium Chloride, Sodium Benzoate, Linalool, Magnesium Carbonate Hydroxide, Benzyl Alcohol, Hexyl Cinnamal, Benzyl Salicylate, Prunus amygdalus dulcis oil, Methylchloroisothiazolinone, Methylisothiazolinone

## **Distributed by:**

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

Made in Mexico

## **Indications:**

helps prevent recurrence of flaking and itching associated with dandruff

## **Principal Display Panel Antidandruff Shampoo 2 in 1 INSTANT MOISTURIZATION**

INSTANT MOISTURIZATION

# **Head & Shoulders**

## Antidandruff Shampoo 2 in 1

# **INSTANT MOISTURIZATION**

3 Action Formula™

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## ***Drug Facts***

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Made in Mexico

**DISTRIBUTED BY:**

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

# NET 12.7 FL OZ (375 mL)

## HEAD AND SHOULDERS 2 IN 1 INSTANT MOISTURIZATION

head and shoulders lotion/shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72389-105
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PYRITHIONE ZINC</b> (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
<b>MAGNESIUM CARBONATE HYDROXIDE</b> (UNII: YQO029V1L4)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>COCO MONOETHANOLAMIDE</b> (UNII: C80684146D)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE (1.7 SUBSTITUENTS PER SACCHARIDE)</b> (UNII: B16G315W7A)	
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>ZINC CARBONATE</b> (UNII: EQR32Y7H0M)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>SODIUM XYLENESULFONATE</b> (UNII: G4LZF950UR)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>LINALOOL, (+)-</b> (UNII: F4VNO44C09)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	

### Packaging

Marketing Start      Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72389-105-02	375 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(72389-105)

### Establishment

Name	Address	ID/FEI	Business Operations
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		812839648	label(72389-105)

Revised: 1/2022

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