

**HEAD AND SHOULDERS 2 IN SOFT AND MANAGEABLE- 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 Soft and Manageable**

**Purpose**

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

The DermaSense balanced pH formula, **eliminates up to 100% of dandruff trace\***, takes care of your scalp and leaves your hair

beautiful,

\*Visible dandruff, using it often.

**Active Ingredient**

<b>Active Ingredient.....</b>	<b>Purpose</b>
Pyrrithione 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 lauryl sulfate, sodium laureth sulfate, glycol distearate, dimethicone, zinc carbonate, sodium chloride, sodium xylenesulfonate, cocamidopropyl betaine, parfum, sodium benzoate, guar hydroxypropyltrimonium chloride, hydrochloric acid, hexyl cinnamal, linalool, magnesium carbonate hydroxide, methylchloroisothiazolinone, FD&C Blue 1, methylisothiazolinone, D&C Red.33

### **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 Soft and Manageable**

## **Head & Shoulders** Antidandruff Shampoo 2 in 1 **Soft and manageable**

Softens hair from root to tip

\*Up to 100% dandruff free

3 Action Formula™

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

The DermaSense balanced pH formula, **eliminates up to 100% of dandruff trace\***, takes care of your scalp and leaves your hair beautiful.

\*Visible dandruff, using it often.

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# Drug Facts

**Active ingredient**

Pyrrithione Zinc 1%.....

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**Indications:** helps prevent recurrence of flaking and itching associated with dandruff.

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**Directions**

- shake well before use. ■ apply in wet hair ■ massage onto scalp. ■ rinse
- repeat if 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 lauryl sulfate, sodium laureth sulfate, glycol distearate, zinc carbonate, sodium chloride, sodium xylenesulfonate, dimethicone, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, hydrochloric acid, benzyl benzoate, magnesium carbonate hydroxide, limonene, linalool, benzyl salicylate, hexyl cinnamal, methylchloroisothiazolinone, FD&C Blue 1, methylisothiazolinone, D&C Red 33.

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## 33.8 FL OZ (1 L)

**HEAD AND SHOULDERS 2 IN SOFT AND MANAGEABLE**

head and shoulders lotion/shampoo

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72389-103
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKNK9TU)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<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>LINALOOL, (-)-</b> (UNII: 3U21E3V8I2)	
<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>SODIUM XYLENESULFONATE</b> (UNII: G4LZF950UR)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<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>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>BENZYL BENZOATE</b> (UNII: N863NB338G)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72389-103-01	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2018	
2	NDC:72389-103-02	375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2018	
3	NDC:72389-103-03	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/26/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/26/2018	

**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(72389-103)

### Establishment

Name	Address	ID/FEI	Business Operations
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		812839648	label(72389-103)

Revised: 1/2022

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