

**HEAD AND SHOULDERS APPLE FRESH- 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 Apple Fresh**

**Purpose**

Clean hair with a long-lasting and fresh aroma

\*Up to 100% dandruff free

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

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**

**Active Ingredient.....Purpose**

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 Lauryl Sulfate, Sodium Laureth Sulfate, Glycol Distearate, Dimethicone, Zinc Carbonate, Sodium Chloride, Sodium Xylenesulfonate, Cocamidopropyl Betaine, Fragrance, Sodium Benzoate, Guar Hydroxypropyltrimonium Chloride, Hydrochloric Acid, Magnesium Carbonate Hydroxide, Hexyl Cinnamal, FD&C Yellow No. 5, Methylchloroisothiazolinone, FD&C Blue 1 and 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 APPLE FRESH**

APPLE FRESH

# Head & Shoulders

## Antidandruff Shampoo

### APPLE FRESH

3 Action Formula™

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### ***Drug Facts***

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**12.68 FL. OZ (375 ML)**

## **HEAD AND SHOULDERS APPLE FRESH**

head and shoulders lotion/shampoo

### **Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:72389-104

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

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
MAGNESIUM CARBONATE HYDROXIDE (UNII: YQO029V1L4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
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)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72389-104-02	375 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/27/2018	
2	NDC:72389-104-03	180 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/27/2018	

<b>Marketing Information</b>			
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.		8 128 0 7550	manufacture(72389-104)

## Establishment

Name	Address	ID/FEI	Business Operations
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		8 128 39 648	label(72389-104)

Revised: 9/2018

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