

**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.

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 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

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 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 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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...the combination salicylic acid formula, **eliminates up to 100% of dandruff trace***, takes care of your scalp and leaves your hair beautiful.

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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
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
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)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	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	
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(72389-104)	

Establishment				
Name	Address	ID/FEI	Business Operations	
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		812839648	label(72389-104)	

Revised: 1/2022

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