

HEAD AND SHOULDERS 2 IN RENEWING CLEANSE- 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 2 in 1 Renewing Cleanse

Purpose

Cleans and deeply conditions dry hair

*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, 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 RENEWING CLEANSE

RENEWING CLEANSE

Head & Shoulders

Antidandruff Shampoo 2 in 1 Renewing Cleanse

Cleans and deeply conditions dry hair

*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

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Drug Facts

Active ingredient

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Directions

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- 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, dimethicone, zinc carbonate, sodium chloride, sodium xylenesulfonate, cocamidopropyl betaine, fragrance, sodium benzoate, guar hydroxypropyltrimonium chloride, hydrochloric acid, hexyl cinnamal, linalool, magnesium carbonate hydroxide, methylchloroisothiazolinone, FD&C Blue 1, methylisothiazolinone, D&C Red 33.

Made in Mexico

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12.7 FL OZ (375 mL)

HEAD AND SHOULDERS 2 IN RENEWING CLEANSE

head and shoulders lotion/shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72389-107
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
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	
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)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72389-107-02	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(72389-107)

Establishment

Name	Address	ID/FEI	Business Operations
ULTRA DISTRIBUCIONES INTERNACIONALES, S.A. DE C.V.		812839648	label(72389-107)

Revised: 1/2022

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