

MIZANI SCALP CARE ANTIDANDRUFF- pyrithione zinc shampoo
L'Oreal USA Products Inc

Drug Facts

Active ingredient

Pyrithione zinc 1%

Purpose

Antidandruff

Use

helps eliminate recurrence of scalp flaking, scaling, and itching associated with dandruff

Warnings

For external use only

When using this product

do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and consult a physician if

condition worsens or does not improve after regular use

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

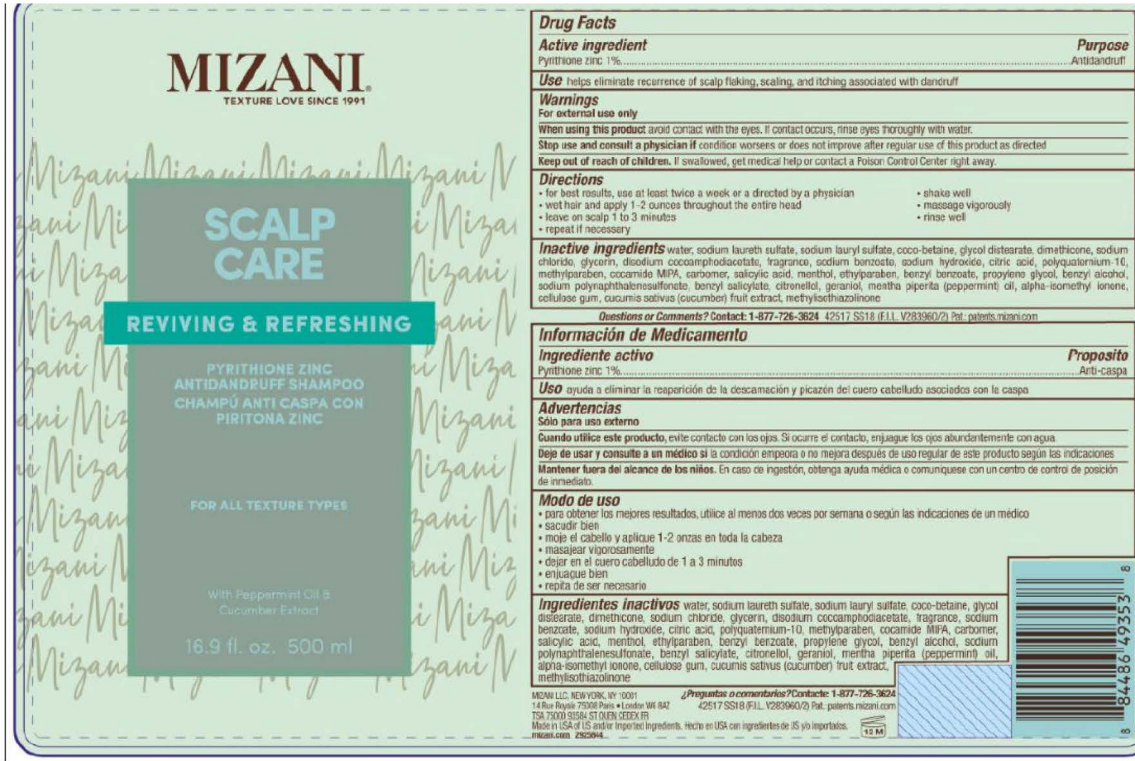
- for best results use at least twice a week or as directed by a physician
- shake well
- wet hair and apply 1 - 2 ounces throughout entire head
- massage vigorously
- leave on scalp 1 to 3 minutes
- rinse well
- repeat if necessary

Inactive ingredients

water, sodium laureth sulfate, sodium lauryl sulfate, coco-betaine, glycol distearate, dimethicone, sodium chloride, glycerin, disodium cocoamphodiacetate, fragrance, sodium benzoate, sodium hydroxide, citric acid, polyquaternium-10, methylparaben, cocamide MIPA, carbomer, salicylic acid, menthol, ethylparaben, benzyl benzoate, propylene glycol, benzyl alcohol, sodium polynaphthalenesulfonate, benzyl salicylate, citronellol, geraniol, mentha piperita (peppermint) oil, alpha-isomethyl ionone, cellulose gum, cucumis sativus (cucumber) fruit extract, methylisothiazolinone

Drug Facts	
Active ingredient Pyrrithione zinc 1%	Purpose Antidandruff
Use helps eliminate recurrence of scalp flaking, scaling, and itching associated with dandruff	
Warnings For external use only When using this product avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. Stop use and consult a physician if condition worsens or does not improve after regular use of this product as directed. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • for best results, use at least twice a week or as directed by a physician • wet hair and apply 1-2 ounces throughout the entire head • leave on scalp 1 to 3 minutes • repeat if necessary • shake well • massage vigorously • rinse well	
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<small>Questions or Comments? Contact: 1-877-726-3624 42517 SS18 (F.I.L. V283960/2) Pat. patents.mizani.com</small>	
Información de Medicamento	
Ingrediente activo Pyrrithione zinc 1%	Propósito Anti-caspa
Uso ayuda a disminuir la reaparición de la descamación y picazón del cuero cabelludo asociados con la caspa	
Advertencias Solo para uso externo Cuando utilice este producto, evite contacto con los ojos. Si ocurre el contacto, enjuague los ojos abundantemente con agua. Deje de usar y consulte a un médico si la condición empeora o no mejora después de uso regular de este producto según las indicaciones. Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un centro de control de posición de inmediato.	
Modo de uso • Para obtener los mejores resultados, utilice al menos dos veces por semana o según las indicaciones de un médico • sacudir bien • moje el cabello y aplique 1-2 onzas en toda la cabeza • masajear vigorosamente • dejar en el cuero cabelludo de 1 a 3 minutos • enjuague bien • repita de ser necesario	
Ingredientes inactivos water, sodium laureth sulfate, sodium lauryl sulfate, coco-betaine, glycol distearate, dimethicone, sodium chloride, glycerin, disodium cocoamphodiacetate, fragrance, sodium benzoate, sodium hydroxide, citric acid, polyquaternium-10, methylparaben, cocamide MIPA, carbomer, salicylic acid, menthol, ethylparaben, benzyl benzoate, propylene glycol, benzyl alcohol, sodium polynaphthalenesulfonate, benzyl salicylate, citronellol, geraniol, mentha piperita (peppermint) oil, alpha-isomethyl ionone, cellulose gum, cucumis sativus (cucumber) fruit extract, methylisothiazolinone	
<small>MIZANI LLC, NEW YORK, NY 10001 42517 SS18 (F.I.L. V283960/2) Pat. patents.mizani.com 14 Rue Royale 75008 Paris 4 Centre 06 942 TSA 75000 PARIS ST OUVEN SEVERE FR Made in USA of US and/or Imported Ingredients, hecho en USA con ingredientes de US y/o importados. mizani.com 2/2014</small>	

C1 - Internal use



Drug Facts

Active ingredient
Pyrrithione zinc 1% **Purpose**
Antidandruff

Use helps eliminate recurrence of scalp flaking, scaling, and itching associated with dandruff

Warnings
For external use only

When using this product: avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water.

Step use and consult a physician if condition worsens or does not improve after regular use of this product as directed

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for best results, use at least twice a week or as directed by a physician
- wet hair and apply 1-2 ounces throughout the entire head
- leave on scalp 1 to 3 minutes
- repeat if necessary
- shake well
- massage vigorously
- rinse well

Inactive ingredients water, sodium lauryl sulfate, sodium lauryl sulfate, coco-betaine, glycol distearate, dimethicone, sodium chloride, glycerin, disodium cocoylphosphate, fragrance, sodium benzoate, sodium hydroxide, citric acid, polyquaternium 15, methylparaben, cocamide MPA, carbomer, salicylic acid, menthol, ethylparaben, benzyl benzoate, propylene glycol, benzyl alcohol, sodium polynaphthalenesulfonate, benzyl salicylate, citronellol, geraniol, mentha piperita (peppermint) oil, alpha-isomethyl ionone, cellulose gum, cucumis sativus (cucumber) fruit extract, methylisothiazolinone

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Información de Medicamento

Ingrediente activo
Pyrrithione zinc 1% **Propósito**
Anti-caspa

Uso ayuda a eliminar la reaparición de la descamación y picazón del cuero cabelludo asociados con la caspa

Advertencias
Solo para uso externo

Cuando utilice este producto, evite contacto con los ojos. Si ocurre el contacto, enjuague los ojos abundantemente con agua

Deje de usar y consulte a un médico si la condición empeora o no mejora después de uso regular de este producto según las indicaciones

Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica e comuníquese con un centro de control de posición de inmediato.

Modo de uso

- para obtener los mejores resultados, utilice al menos dos veces por semana o según las indicaciones de un médico
- sacudir bien
- moje el cabello y aplique 1-2 onzas en toda la cabeza
- masajee vigorosamente
- dejar en el cuero cabelludo de 1 a 3 minutos
- enjuague bien
- repita de ser necesario

Ingredientes inactivos water, sodium lauryl sulfate, sodium lauryl sulfate, coco-betaine, glycol distearate, dimethicone, sodium chloride, glycerin, disodium cocoylphosphate, fragrance, sodium benzoate, sodium hydroxide, citric acid, polyquaternium-15, methylparaben, cocamide MPA, carbomer, salicylic acid, menthol, ethylparaben, benzyl benzoate, propylene glycol, benzyl alcohol, sodium polynaphthalenesulfonate, benzyl salicylate, citronellol, geraniol, mentha piperita (peppermint) oil, methylisothiazolinone

Preguntas o comentarios? Contacte: 1-877-726-3624 42517 SS18 (F.L.L. V283960/2) Pat. patents.mizani.com

MIZANI LLC, NEW YORK, NY 10011
14 Rue Royale 75008 Paris • London W6 8AZ
TSA 75001 SUSA ST OLEN SDEEX FR
Made in USA of US and/or foreign ingredients. Hecho en USA con ingredientes de US y/o importados.
mizani.com Z25094

C1 - Internal use

MIZANI SCALP CARE ANTIDANDRUFF			
pyrrithione zinc shampoo			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-388
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	PYRITHIONE ZINC (UNII: R953O2RHZ 5) (PYRITHIONE ZINC - UNII:R953O2RHZ 5)	PYRITHIONE ZINC	10 mg in 1 mL
Inactive Ingredients			
	Ingredient Name		Strength
	WATER (UNII: 059QF0KO0R)		
	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		

SODIUM LAURYL SULFATE (UNII: 368GB5141J)
COCO-BETAINE (UNII: 03DH2IZ3FY)
GLYCOL DISTEARATE (UNII: 13W7MDN21W)
DIMETHICONE (UNII: 92RU3N3Y1O)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
GLYCERIN (UNII: PDC6A3C0OX)
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
POLYQUATERNIUM-10 (1000 MPA.S AT 2%) (UNII: GMR4PEN8PK)
METHYLPARABEN (UNII: A2I8C7HI9T)
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
SALICYLIC ACID (UNII: O414PZ4LPZ)
MENTHOL (UNII: L7T10EIP3A)
ETHYLPARABEN (UNII: 14255EXE39)
BENZYL BENZOATE (UNII: N863NB338G)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
BENZYL ALCOHOL (UNII: LKG8494WBH)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
GERANIOL (UNII: L837108USY)
PEPPERMINT OIL (UNII: AV092KU4JH)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)
CUCUMBER (UNII: YY7C30VXJT)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-388-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2008	
2	NDC:49967-388-02	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	06/01/2008	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
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L'Oreal USA, Inc.

960317444

manufacture(49967-388)

Revised: 12/2023

L'Oreal USA Products Inc