

ALEVAI - STEM CELL ANTI DANDRUFF- pyrithione zinc shampoo
ALEVAI PRODUCTS LLC

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.

81457-020-04
81457-020-08
81457-020-16
81457-020-32

Pyrrithione Zinc..... 2%
Anti-dandruff

Use helps prevent recurrence of flaking and itching associated with dandruff.

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

For external use only.

When using this product do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

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

Shake well. Wet hair. Massage shampoo into 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.

Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.

Aqua, Sodium C14-16 Olefin Sulfonate, Acrylates Copolymer, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Methyl Gluceth-20, Cocamide MEA, Caprylyl Glycol, Hexylene Glycol, Parfum, Sodium Hydroxide, Polyquaternium-7, Mica, Titanium Dioxide, Silica, Iron Oxide, Tin Oxide, Propylene Glycol, Biotin, Malus Domestica Fruit Cell Culture Extract, Xanthan Gum, Sodium Benzoate, Camellia Sinensis Leaf Extract, Disodium EDTA, Hydrolyzed Keratin, Citric Acid, Panthenol, Argania Spinosa Kernel Oil, Cocos Nucifera Oil, Phenoxyethanol, FD&C Blue. 1 (CI 42090), Hexyl Cinnamal, Citral.

ALEVAI - ANTI DANDRUFF SHAMPOO 3.4OZ

Drug Facts	
Active Ingredients	Purpose
Pylichaic Zinc	2% Anti-dandruff
Uses: Use helps prevent recurrence of flaking 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. Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions: Shake well. Wet hair. Massage shampoo into 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.	
Other information: Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.	
Inactive Ingredients: Aqua, Sodium C14-16 Olefin Sulfonate, Acrylates Copolymer, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Methyl Gluceth-20, Cocamide MEA, Caprylyl Glycol, Hexylene Glycol, Parfum, Sodium hydroxide, Polyquaternium-7, Mica, Titanium Dioxide, Silica, Iron Oxide, Tin Oxide, Propylene Glycol, Biotin, Malus Domestica Fruit Cell Culture Extract, Aphanizomenon, Sodium Benzoate, Camellia sinensis Leaf Extract, Disodium EDTA, Hydrolyzed Keratin, Citric Acid, Phosphoric Acid, Arginine, Sodium Chloride, Cocos Nucifera Oil, Phenoxyethanol, FD&C Blue 1 (CI 42090), Hexyl Cinnamal, Citral.	



ALEVAI

STEM CELL
ANTI-DANDRUFF
SHAMPOO

MAXIMUM
STRENGTH

3.4 OZ | 100 ML



Distributed by:
Alevai Products LLC
Clearwater, FL 33758
Questions or comments?
Visit www.Alevai.co

ALEVAI - ANTI DANDRUFF SHAMPOO 8OZ

Drug Facts	
Active ingredients:	Purpose:
Pythione Zinc	2% Anti-dandruff
Uses: Use helps prevent recurrence of flaking 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. Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions: Shake well. Wet hair. Massage shampoo into scalp. Rinse. Repeat if desired. For best results, use at least once a week, or as directed by a doctor. For maximum dandruff control, use every time you shampoo.	
Other information: Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.	
Inactive ingredients: Aqua, Sodium C14-16 Olefin Sulfonate, Acrylates Copolymer, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Methyl Gluceth-20, Cocamide MEA, Capryl Glycol, Hexylene Glycol, Parfum, Sodium Hydroxide, Polyquaternium-7, Mica, Titanium Dioxide, Silica, Iron Oxide, Tri Oxide, Phosphoric Glycol, Beeswax, Madia Domestica Fruit Cell Culture Extract, Kaohae Gum, Sodium Benzoate, Canella Winteria Leaf Extract, Disodium EDTA, Hydrolyzed Keratin, Citric Acid, Panthenol, Argania Spinosa Kernel Oil, Cassia Nuttallia Oil, Phenylpropanediol, FD&C Blue 1 (CI 42090), Hexyl Cinnamal, Citral.	



PARABEN FREE



SULFATE FREE



STEM CELL TECHNOLOGY



VEGAN



CRUELTY FREE



MADE IN THE USA

ALEVAI

STEM CELL ANTI-DANDRUFF SHAMPOO

MAXIMUM
STRENGTH

8 OZ

236 ML



NDC#: 81457-020-08
Distributed by:
Alevai Products LLC
Clearwater, FL 33756
Questions or comments?
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ALEVAI - ANTI DANDRUFF SHAMPOO 16OZ

Drug Facts	
Active Ingredients	Purpose
Pythione Zinc	2% Anti-Dandruff
Uses:	
Use helps prevent recurrence of flaking 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.	
Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions:	
Shake well. Wet hair. Massage shampoo into 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.	
Other Information:	
Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.	
Inactive Ingredients:	
Aqua, Sodium C14-16 Olefin Sulfonate, Acrylates Copolymer, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Methyl Gluceth-20, Cocamide MEA, Caprylyl Glycol, Hexylene Glycol, Parfum, Sodium Hydroxide, Polydimethylsiloxane-7, Mica, Titanium Dioxide, Silica, Iron Oxide, Tin Oxide, Propylene Glycol, Biotin, Malus Domestica Fruit Cell Culture Extract, Xanthan Gum, Sodium Benzoate, Camellia Sinensis Leaf Extract, Disodium EDTA, Hydroxytoluene, Citric Acid, Parthenol, Argania Spinosa Kernel Oil, Cocos Nucifera Oil, Phenoxyethanol, FD&C Blue 1 (CI 42090), Hexyl Cinnamal, Citral.	



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PARABEN FREE



SULFATE FREE



STEM CELL TECHNOLOGY



VEGAN



CRUELTY FREE



MADE IN THE USA

ALEVAI

STEM CELL
ANTI-DANDRUFF
SHAMPOO

MAXIMUM
STRENGTH

16 OZ

473 ML

ALEVAI - ANTI DANDRUFF SHAMPOO 32OZ

Drug Facts	
Active Ingredients	Purpose 2% Anti-dandruff
Uses: Use twice prevent recurrence of flaking 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. Keep out of reach of children. If swallowed, get medical help, or contact a Poison Control Center right away.	
Directions: Shake well. Wet hair. Massage shampoo into 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.	
Other information: Stop use and ask a doctor if condition worsens or does not improve after regular use as directed.	
Inactive Ingredients: Aqua, Sodium C14-16 Olefin Sulfonate, Acrylates Copolymer, Cocamidopropyl Betaine, Cocamidopropylamine Oxide, Methyl Gluceth-20, Cocamide MEA, Caprylyl Glycol, Hexylene Glycol, Potassium Hydroxide, Polyquaternium-7, Mica, Titanium Dioxide, Zinc Oxide, Tin Oxide, Propylene Glycol, Biotin, Malva Domestica Fruit Cell Culture Extract, Xanthan Gum, Sodium Benzoate, Camellia Sinensis Leaf Extract, Disodium EDTA, Hydrolyzed Keratin, Citric Acid, Phthalenol, Argania Spinosa Kernel Oil, Cocos Nucifera Oil, Phenylethyl Alcohol, FD&C Blue 1 (CI 42090), Hexyl Cinnamal, Citral.	



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 Clearwater, FL 33756
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ALEVAI

STEM CELL
 ANTI-DANDRUFF
 SHAMPOO

MAXIMUM
 STRENGTH
 32 OZ | 946 ML

ALEVAI - STEM CELL ANTI DANDRUFF

pyrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81457-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCO MONOETHANOLAMIDE (UNII: C80684146D)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
STANNIC OXIDE (UNII: KM7N50LOS6)
ARGANIA SPINOSA WHOLE (UNII: 83K6O4FR76)
XANTHAN GUM (UNII: TTV12P4NEE)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
COCAMIDOPROPYLAMINE OXIDE (UNII: M4SL82J7HK)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
PANTHENOL (UNII: WW9CM0O67Z)
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
BIOTIN (UNII: 6SO6U10H04)
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
WATER (UNII: 059QF0KO0R)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SODIUM BENZOATE (UNII: OJ245FE5EU)
MALUS DOMESTICA WHOLE (UNII: 04W636S1V3)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81457-020-08	226 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2021	
2	NDC:81457-020-16	453 g in 1 BOTTLE; Type 0: Not a Combination Product	11/12/2021	
3	NDC:81457-020-04	96 g in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2022	
4	NDC:81457-020-32	906 g in 1 BOTTLE; Type 0: Not a Combination Product	06/17/2022	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	M032	11/12/2021	

Labeler - ALEVAI PRODUCTS LLC (117842557)

Registrant - CHEMCO CORPORATION (032495954)

Establishment

Name	Address	ID/FEI	Business Operations
CHEMCO CORPORATION		032495954	manufacture(81457-020)

Revised: 7/2022

ALEVAI PRODUCTS LLC