

ANTIDANDRUFF- pyrithione zinc shampoo
BBCOS S.R.L.

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.

GREEN CARE ESSENCE ANTI-DANDRUFF SHAMPOO

These highlights do not include all the information needed to use see full prescribing information for Initial U.S. Approval

Active Ingredient:

Pyrithione Zinc 1%

Uses:

Fights and helps prevents recurrence of flaking and itching associated with dandruff

Warnings:

For external use only.

When using this product:

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop using this product and consult a doctor:

if conditions worsen 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 Center immediately.

Directions:

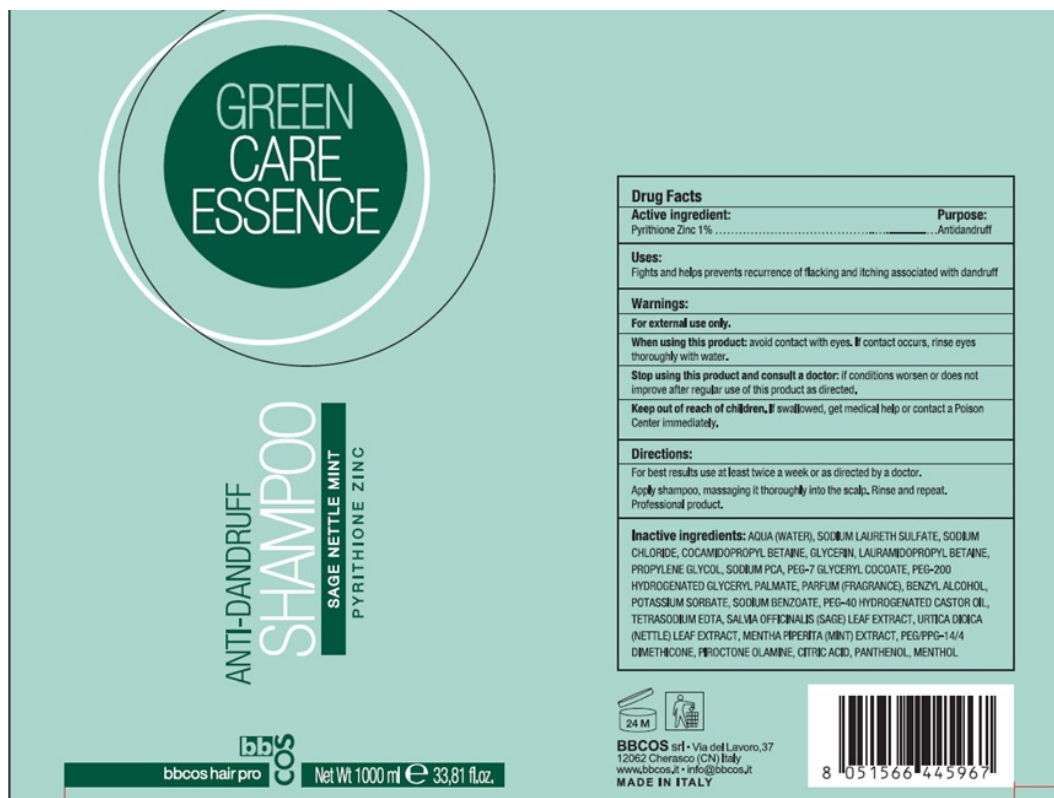
For best results use at least twice a week or as directed by a doctor.

Apply shampoo, massaging it thoroughly into the scalp. Rinse and repeat.

Professional product.

Inactive ingredients:

AQUA (WATER), SODIUM LAURETH SULFATE, SODIUM CHLORIDE, COCAMIDOPROPYL BETAINE, GLYCERIN, LAURAMIDOPROPYL BETAINE, PROPYLENE GLYCOL, SODIUM PCA, PEG-7 GLYCERYL COCOATE, PEG-200 HYDROGENATED GLYCERYL PALMATE, PARFUM (FRAGRANCE), BENZYL ALCHOL, POTASSIUM SORBATE, SODIUM BENZOATE, PEG-40 HYDROGENATED CASTOR OIL, TETRASODIUM EDTA, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, URTICA DIOICA (NETTLE) LEAF EXTRACT, MENTHA PIPERITA (MINT) EXTRACT, PEG/PPG-14/4 DIMETHICONE, PIROCTONE OLAMINE, CITRIC ACID, PANTHENOL, MENTHOL



Drug Facts	
Active ingredient: Pyrrithione Zinc 1%	Purpose: ... Antidandruff
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GREEN
 CARE
 ESSENCE
 ANTI-DANDRUFF
 SHAMPOO
 SAGE NETTLE MINT
 PYRITHIONE ZINC

ANTIDANDRUFF

pyrrithione zinc shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70549-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	10 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	


WATER (UNII: 059QF0KO0R)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
GLYCERIN (UNII: PDC6A3C0OX)
LAURAMIDOPROPYL BETAINE (UNII: 23D6XVI233)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
PEG-7 GLYCERYL COCOATE (UNII: VNX7251543)
PEG-200 HYDROGENATED GLYCERYL PALMATE (UNII: W161T051Y1)
EDETATE SODIUM (UNII: MP1J8420LU)
BENZYL ALCOHOL (UNII: LKG8494WBH)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SODIUM BENZOATE (UNII: OJ245FE5EU)
PEG/PPG-14/4 DIMETHICONE (UNII: 646XNV22YX)
PIROCTONE OLAMINE (UNII: A4V5C6R9FB)
PANTHENOL (UNII: WV9CM0O67Z)
MENTHOL (UNII: L7T10EIP3A)
SAGE (UNII: 065C5D077J)
URTICA DIOICA LEAF (UNII: X6M0DRN46Q)
MENTHA PIPERITA (UNII: 79M2M2UDA9)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	3mm
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70549-123-11	1000 mg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2016	
2	NDC:70549-123-22	250 mg in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2016	



GREEN CARE ESSENCE

ANTI-DANDRUFF SHAMPOO


SAGE NETTLE MINT
PYRITHIONE ZINC

bbcos hair pro **bbcos**


Net Wt 1000 ml e 33.81 fl.oz.

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358 H	06/01/2016	

Labeler - BBCOS S.R.L. (434126395)

Revised: 5/2016

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