

SEBEX- salicylic acid, colloidal sulfur shampoo
Rugby Laboratories

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.

Sebex Shampoo

Active ingredient

Colloidal sulfur, 2%
Salicylic acid, 2%

Purpose

Antidandruff

Use

- Controls the symptoms of:
 - Dandruff
 - Seborrheic dermatitis
 - Psoriasis

Warning

For external use only

For external use only

For external use only

Do not use

Do not use for seborrheic dermatitis or psoriasis if condition covers a large area of the body

Ask a doctor before use if you have

Ask a doctor or pharmacist before use if you are

When using this product

- avoid contact with eyes
- if contact occurs, rise eyes thoroughly with water

Stop use and ask a doctor if

condition worsens or does not improve after regular use

Pregnancy/breast-feeding warning

Keep out of reach of children

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

Directions

- SHAKE WELL BEFORE USE
- wet the scalp or skin and massage in enough shampoo to work up a lather
- massage for 3-5 minutes and rinse out thoroughly
- repeat application and rinse thoroughly again
- for best results, use at least twice a week or as directed by a doctor

Other information

- store at room temperature
- see container for Lot Number and Expiration Date

Inactive ingredients

Disodium cocoamphodipropionate, docusate sodium, fragrance, hydrochloric acid, isopropyl palmitate, octoxynol-1, PEG 85 lanolin, purified water, quaternium-15, sodium lauryl sulfate

Questions?

Questions or comments?

Call 1-800-645-2158

Principal Display Panel

SEBEX

Medicated Dandruff, Seborrheic Dermatitis & Psoriasis Shampoo

Drug Facts (continued)
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Questions or comments?
Call 1-800-645-2158, 9 am - 5 pm ET, Monday - Friday

NDC 0536-1962-97

Rugby

Sebex

Medicated Dandruff, Seborrheic Dermatitis & Psoriasis Shampoo

TAMPER EVIDENT: BOTTLE HAS OVER-WRAP SEAL. DO NOT USE IF SEAL IS TORN, BROKEN OR MISSING

Net Contents
4 fl oz (118 mL)

Drug Facts	
Active ingredients	Purpose
Colloidal sulfur, 2%	} Antidandruff
Salicylic acid, 2%	
Uses	controls the symptoms of
■ dandruff	■ seborrheic dermatitis
■ psoriasis	
Warnings	
For external use only	
Do not use for seborrheic dermatitis or psoriasis if condition covers a large area of the body	
When using this product	
■ avoid contact with eyes	
■ if contact occurs, rinse eyes thoroughly with water	
Stop use and ask a doctor 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.	



Mfd for: Rugby Laboratories, Inc.
Duluth, Georgia 30097
www.rugbylaboratories.com R0811

SEBEX

salicylic acid, colloidal sulfur shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1962
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
salicylic acid (UNII: O414PZ4LPZ) (salicylic acid - UNII:O414PZ4LPZ)	salicylic acid	20 mg in 1000 mL
sulfur (UNII: 70FD1KFU70) (sulfur - UNII:70FD1KFU70)	sulfur	20 mg in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
DISODIUM CO CO AMPHODIPROPIONATE (UNII: 6K8PRP397M)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
OCTOXYNOL-1 (UNII: 20CAX7IO75)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
LANOLIN (UNII: 7EV65EAW6H)	
WATER (UNII: 059QF0KO0R)	
QUATERNIUM-15 (UNII: E40U03LEM0)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	BLUE (Aqua Blue)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1962-97	118 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	10/29/2012	

