

SALICYLIC ACID- salicylic acid soap
D3 Development, Inc.

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.

Dermaharmony Salicylic Acid Soap

Drug Facts

Active ingredient

Salicylic acid 2%

Purpose

Acne treatment

Uses

- For the treatment of acne
- Reduces the number of acne pimples and allows skin to heal
- Penetrates pores to clear most acne blemishes
- Dries up acne pimples
- Helps keep skin clear of new acne blemishes, acne pimples, whiteheads, and blackheads

Warnings

For external use only

When using this product, skin irritation and dryness may occur if you use other topical acne medications at the same time or immediately following use of this product. If this occurs, use only one medication at a time unless directed by a doctor.

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

Directions

- Apply liberally over wet skin with a clean wash cloth or body puff, concentrating on areas prone to acne, avoiding contact with eyes.
- Rinse thoroughly and pat dry with a clean towel
- Because bothersome dryness of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

Other information

- Store at room temperature
- Lot number and expiration date are printed on back panel.

Inactive ingredients

Sodium palmate, sodium cocoate*, sodium palm kernelate*, water, glycerin, titanium dioxide, table salt, olive oil, Avena Sativa (oat) kernel flour, pentasodium pentetate, tocopheryl acetate (vitamin E)

Questions?

1-800-827-3730

www.dermaharmony.com

Distributed by:

D3 Development, Inc., Portland, ME 04101

Made in the USA

dermaharmony

Salicylic Acid SOAP

For Acne, Whiteheads, & Blackheads

NET WT 4.0 OZ (113 G)

Drug Facts (continued)		
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SALICYLIC ACID

salicylic acid soap

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:718 19-003

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOATE (UNII: R1TQH25F4I)	
GLYCERIN (UNII: PDC6A3C0OX)	
OATMEAL (UNII: 8PI54V663Y)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
PENTASODIUM PENTETATE (UNII: 961TOZ5L7T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71819-003-04	113 g in 1 CELLO PACK; Type 0: Not a Combination Product	05/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	05/04/2018	

Labeler - D3 Development, Inc. (043195877)

Revised: 5/2018

D3 Development, Inc.