

GLYTONE ACNE SELF-FOAMING CLEANSER- salicylic acid gel
Genesis Pharmaceutical, 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.

Glytone Acne Self-Foaming Cleanser

Active ingredients Purpose

Salicylic Acid 0.5% Acne Treatment

Acne treatment

Use For the treatment of acne.

- Dries and clears acne blemishes and allows skin to heal.
- Penetrates pores to eliminate most acne blemishes, blackheads, and whiteheads.
- Helps prevent the development of new acne blemishes, blackheads, and whiteheads.

Warnings:

For external use only.

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if rash occurs

Keep out of reach of children.

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

Directions

- At initial use, turn pump head counter-clockwise to unlock.
- Dispense a small amount into your hand and mix with a little water.
- Apply a thin layer over entire affected area in a circular motion and rinse thoroughly with warm water two times daily. For a mask-like effect, leave on for 30 seconds before rinsing.
- Because of excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Water, Methyl Perfluoroisobutyl Ether, Butylene Glycol, Sorbitol, Methyl Perfluorobutyl Ether, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Chondrus Crispus (Carrageenan), Cyclopentasiloxane, Cyclohexasiloxane, Sodium Cocamidopropyl PG-Dimonium Chloride Phosphate, Polyhydroxystearic acid, Isononyl Isononanoate, Ethylhexyl Isononanoate, Xanthan Gum, Sodium Hydroxide, Perfluorohexane, o-Cymen-5-ol, Tetrasodium EDTA, Cinnamomum Zeylanicum Bark Extract, Oryza Sativa (Rice) Bran Extract, Yeast Polysaccharides, Blue 1 (CI 42090)

Drug Facts

Active Ingredients	Purpose
Salicylic Acid 0.5 %	Acne Treatment

Use For the treatment of acne.

- Dries and clears acne blemishes and allows skin to heal.
- Penetrates pores to eliminate most acne blemishes, blackheads, and whiteheads.
- Helps prevent the development of new acne blemishes, blackheads, and whiteheads.

Warnings
For external use only.

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid contact with eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if rash occurs

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

Directions

- At initial use, turn pump head counter-clockwise to unlock.
- Dispense a small amount into your hand and mix with a little water.
- Apply a thin layer over the entire affected area in a circular motion and rinse thoroughly with warm water two times daily. For a mask-like effect, leave on for 30 seconds before rinsing.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor.
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive Ingredients
Water, Methyl Perfluoroisobutyl Ether, Butylene Glycol, Sorbitol, Methyl Perfluorobutyl Ether, Cocamidopropyl Betaine, Sodium Laureth Sulfate, Camageenan, Cyclopentasiloxane, Cyclohexasiloxane, Phenoxyethanol, Sodium Cocamidopropyl PG-Dimonium Chloride Phosphate, Polyhydroxystearic Acid, Isononyl Isononanoate, Ethylhexyl Isononanoate, Xanthan Gum, Sodium Hydroxide, Perfluorohexane, o-Cymen-5-ol, Tetrasodium EDTA, Cinnamomum Zeylanicum Bark Extract, Oryza Sativa (Rice) Bran Extract, Yeast Polysaccharides, Blue 1



Pierre Fabre

Distributed by:
Genesis Pharmaceutical, Inc.
a subsidiary of Pierre Fabre
Parsippany, NJ 07054
Made in U.S.A.
1-800-GLYTONE(459-8663)
www.glytone-usa.com

2367F

Glytone Acne Self-Foaming Cleanser is a unique, non-irritating formula that washes away surface debris, clears pores and gently exfoliates. Its self-foaming technology prolongs contact of Salicylic Acid with the skin for better efficacy in blemish control. For a deeper mask-like cleanse, leave on for 30 seconds before rinsing.

GLYTONE

Acne
Self-Foaming
Cleanser

0.5

Salicylic Acid

NON-IRRITATING FORMULA

180 mL / 6.1 FL. OZ.

Glytone Acne Self-Foaming Cleanser

0.5 salicylic acid

non-irritating formula

180 ml/6.1 fl oz

GLYTONE ACNE SELF-FOAMING CLEANSER

salicylic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64760-303
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	5 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	PERFLEXANE (UNII: FX3WJ41CMX)			
	POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)			
	O-CYMEN-5-OL (UNII: H41B6Q19L)			
	WATER (UNII: 059QF0KO0R)			
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
	SORBITOL (UNII: 506T60A25R)			
	BETAINE (UNII: 3SCV180C9W)			
	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
	CARRAGEENAN (UNII: 5C69YCD2YJ)			
	CYCLOMETHICONE 5 (UNII: 0THT5PC10R)			
	CYCLOMETHICONE 6 (UNII: XHK3U310BA)			
	COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)			
	ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)			
	XANTHAN GUM (UNII: TTV12P4NEE)			
	SODIUM HYDROXIDE (UNII: 55X04QC32I)			
	EDETATE SODIUM (UNII: MP1J8420LU)			
	YEAST (UNII: 3NY3SM6B8U)			
	RICE BRAN (UNII: R60QEP13IC)			
	FD&C BLUE NO. 1 (UNII: HBR47K3TBD)			
	METHYL PERFLUOROBUTYL ETHER (UNII: H637A50B7U)			
	CINNAMON BARK OIL (UNII: XE54U569EC)			
	METHYL PERFLUOROISOBUTYL ETHER (UNII: HI89P35AAX)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-303-02	1 in 1 CARTON	09/16/2015	
1		180 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	09/16/2015	05/31/2021	

Labeler - Genesis Pharmaceutical, Inc. (117196928)

