

SA OIL FREE CREAM- salicylic acid cream cream
Essay Cosmetics Group 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.

SA Oil Free Cream-Essay

Active Ingredient

Acne medication, 1% Salicylic Acid

Acne Medication

Use

Use ■ for treatment of acne

Warnings ■ for external use only ■ 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

Directions ■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer one to three times daily ■ because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three 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, Glycerin, Dimethicone, Cetyl Alcohol, Propanediol, Isopropyl Myristate, Glyceryl Stearate, PEG-100 Stearate, Behentrimonium Methosulfate, Bisabolol, Cyclomethicone, Allantoin, Butylene Glycol, Tocopheryl Acetate, Propylene Glycol, Disodium EDTA, Diazolidinyl Urea, Iodopropynyl Butylcarbamate

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

- clean the skin thoroughly before applying this product
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Principal Display Panel

The image shows the front of the product packaging. At the top is the Essay logo, a water drop icon, and the text 'ESSAY®'. Below that is 'SA Oil Free Cream' in large bold letters. Underneath is 'pH 3.5-4.0 Mild & Effective' in a dark oval. Below that is '-Acne Medication-' with an OTC logo. A list of four benefits is provided: 1. Clears up acne blemishes and allows skin to heal; 2. Penetrates pores to clear most of blackheads / whiteheads; 3. Helps prevent new acne pimples from forming; 4. Skin moisturizing effect. At the bottom, it says '1.7 FL OZ (50 ml)'.

Drug Facts	
Active ingredient Salicylic acid 1%	Purpose Acne Medication
Use For the treatment of acne	
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.	
Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.	
Directions ■ clean the skin thoroughly before applying this product ■ cover the entire affected area with a thin layer one to three times daily ■ because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor ▶	

Drug Facts	(continued)
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MKTG by Essay Cosmetics Group LLC
120 W Central Ave. Winter Haven FL 33880
Made in USA

SA OIL FREE CREAM

salicylic acid cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72900-882
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 0.5 g

Inactive Ingredients

Ingredient Name	Strength
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PEG-100 STEARATE (UNII: YD01N1999R)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9)	
1,2-PROPANEDIOL, 1-BENZOATE (UNII: K4K90ZQ89N)	
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72900-882-70	0.5 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/28/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	02/28/2019	

