# SA OIL FREE SERUM- salicylic acid serum gel 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.

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**SA Oil Free Serum-Essay** 

# **Active Ingredient**

**Active Ingredient** 1.2% Salicylic Acid

### Purpose

Acne Medication

■ apply evenly to the affected area one to two times daily

#### **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**

**Inactive ingredients** Water, PEG-7 Glyceryl Cocoate, Propanediol, Glycerin, PEG-40 Hydrogenated Castor Oil, Cocamidopropyl dimethylamine, Glycine Betaine, Dipotassium Glycyrrhizinate, Bisabolol, Allantoin, Xanthan Gum, Hydroxyethylcellulose, Sodium Gluconate, Propylene Glycol, Diazolidinyl Urea, Lodopropynyl Butylcarbamate, Sodium Hydroxide

#### KEEP OUT OF REACH OF CHILDREN

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

#### **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 pealing occurs, reduce application to once a day or every other day

**Warnings** ■ 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

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#### **Principal Display Panel**



pH 3.5 - 4.0 Mild & Effective

-Acne Medication- 🗽

- Clears up acne pimples and allows skin to heal
- Penetrates pores to clear most of blackheads
   / whiteheads
- 3. Helps prevent new acne blemishes from forming

2 FL OZ (60 ml)

# **Drug Facts**

**Active ingredient Purpose** Salicylic Acid 1.2 % ....... 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 ■

# Drug Facts

(continued)

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, Propanediol, Glycerin, Cocamidopropyl dimethylamine, Glycine Betaine, Dipotassium Glycyrrhizinate, Allantoin, Xanthan Gum, Hydroxyethylcellulose, Sodium Gluconate, Propylene Glycol, Diazolidinyl Urea, Iodopropynyl Butylcarbamate



MKTG by Essay Cosmetics Group LLC 120 W Central Ave. Winter Haven FL 33880

Made in USA

#### SA OIL FREE SERUM

salicylic acid serum gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72900-008

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)
SALICYLIC ACID
0.72 g in 0.72 g

Inactive Ingredients			
Ingredient Name	Strength		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
CO CAMIDO PRO PYL DIMETHYLAMINE (UNII: L36 BM7DG2T)			
SODIUM GLUCONATE (UNII: R6Q3791S76)			
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)			
BETAINE (UNII: 3SCV180C9W)			
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0 FE3FX)			
PROPANEDIOL (UNII: 5965N8W85T)			
ALLANTO IN (UNII: 344S277G0Z)			
XANTHAN GUM (UNII: TTV12P4NEE)			
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)			

Ш	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date

	0.72 g in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	0 2/28/20 19				
Marketing Information						
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part333D	02/28/2019				

# Labeler - Essay Cosmetics Group, LLC (085448126)

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