# PCA GEL- salicylic acid gel CP Skin Health Group, 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.

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#### **PCA SKIN Acne Gel Advanced Treatment**

## **Active Ingredients**

Salicylic Acid 2%

### **Purpose**

Acne Treatment

#### Uses

- For the treatment of acne
- Helps keep skin clear of new acne pimples, blackheads or 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 medication at a time.

Keep out of reach of children.

If product is 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
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

# **Inactive Ingredients**

Alcohol, Butylene Glycol, Cellulose, Denatonium Benzoate, Ethoxydiglycol, Ethyl Linoleate, Hexylresorcinol, Hydroxyethylcellulose, Isopentyldiol, Mandelic Acid, Pentylene Glycol, Polyacrylate Crosspolymer-6, Polyglyceryl-10 Dioleate, Polyglyceryl-10 Dipalmitate,

# Potassium Hydroxide, Sodium Acetate, t-Butyl Alcohol, Water

		PCA skini	
Drug Facts  Active ingredient Purpose Salicylic acid 2% Acne treatment  Uses For the treatment of acne, Helps keep skin clear of new acne pimples, blackheads, or 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.  If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	Drug Facts (continued)  Directions (continued)  If bothersome dryness or peeling occurs, reduce application to once a day or every other day  Other information  Protect this product from excessive heat and direct sun.  Inactive ingredients Water/Aqua/Eau, SD Abohol 40-B, Ethooydighycol, Azəlaic Acid, Pentylene Glycol, Fotassium Hydroxyethylcellulose, Bulylene Glycol, Fotassium Hydroxyethylcellulose, Bulylene Glycol, Potassium Hydroxyethylcellulose, Glabra (Licorice) Boot Extract, Cinnamomum Cassia Bark Extract, Poterium Officinale Root Extract, Zingiber Officinale (Ginger) Root Extract, Questions or comments? 877,722,7546	acne gel gel anti-acné	the PCA SKIN philosophy: to improve people's lives through advanced professional skincare treatments, clinical education, and superior results. formulated without: synthetic dyes synthetic fragrances parabens no animal testing: PCA SKIN does not perform or condone animal testing.
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.	Questions or concerns? Call: 877.PCA,SKIN [722,7546] in U.S. pcaskin.com   @ please recycle © 2019 Physicians Care Alliance, LLC Scottsdale, AZ 85251   Made in U.S.A. Manufactured for Physicians Care Allance, LLC	<b>℮</b> 1 fl oz/29 <b>.</b> 5mL	consult your OB/GYN prior to using this product if you are pregnant, may become pregnant, or are lactating.

# **PCA GEL**

salicylic acid gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68726-445
Route of Administration	TOPICAL		

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ) SALICYLIC ACID (2 g in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
ALCOHOL (UNII: 3K9958V90M)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)		

DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ETHYL LINOLEATE (UNII: MJ2YTT4J8M)	
HEXYLRESORCINOL (UNII: R9QTB5E82N)	
ISOPENTYLDIOL (UNII: 19NOL5474Q)	
MANDELIC ACID (UNII: NH496X0UJX)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED	
(45000 MPA.S) (UNII: Q7UI015FF9)	
(45000 MPA.S) (UNII: Q7UI015FF9) POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH)	
POLYGLYCERYL-10 OLEATE (UNII: 55C81W76DH) POLYGLYCERYL-10 DIPALMITATE (UNII: 84VD0IA2S6)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68726- 445-02	1 in 1 CARTON	08/01/2020	
1	NDC:68726- 445-01	29.5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:68726- 445-03	7.3 mL in 1 TUBE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	08/01/2020	

# Labeler - CP Skin Health Group, Inc (611921669)

Revised: 11/2022 CP Skin Health Group, Inc