KLEER-PLEX PENETRATING ACNE- salicylic acid gel Bio-Medical & Pharmaceutical Manufacturing Corporation

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.

Drug Facts

Acne Treatment Gel

Active Ingredients

Salicylic Acid, 2%

Purpose

Acne Treatment

Use

For the management of acne.

Clears up most acne pimples, blackheads, and whiteheads and allows skin to heal. Penetrates pores to eliminate most acne blemishes.

Helps prevent new acne pimples.

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

KEEP OUT OF REACH OF CHILDREN

Directions

Each night, dispense a small amount of gel onto the fingertips.

Spread gel sparingly on the face and other affected areas using small circular motions avoiding the eyes.

Repeat after perspiration or makeup use.

If dryness occurs, reduce frequency to once each day.

Sensitivity test for a new user

Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

Inactive Ingredients

Purified Water, Alcohol, Glycerin, Xanthan Gum, Polysorbate 20, Peppermint Oil, (.Alpha.-Tocopherol Acetate), Wheat Germ Oil, Glycolic Acid, Tert-Butyl Alcohol, Brucine Sulfate.

Questions or comments

281-835-8051 M-F 8 AM to 5 PM

NDC 37945-874-11





DRUG FACTS

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PENETRATING ACNE GEL

1

1 fl oz | 30 ml

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MANUFACTURED BY

BIO-MEDICAL & PHARM. MFG. CORP. 4311 SOUTH DR., HOUSTON, TX 77053 KLEERPLEX.COM

KLEER-PLEX PENETRATING ACNE

salicylic acid gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:37945-874

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)

SALICYLIC ACID

SALICYLIC ACID

20 mg in 1 mL

Inactive Ingredients Ingredient Name Strength BRUCINE SULFATE (UNII: KY7012XPOQ) WATER (UNII: 059QF0K00R) ALCOHOL (UNII: 3K9958V90M) GLYCERIN (UNII: PDC6A3C00X)

XANTHAN GUM (UNII: TTV12P4NEE)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WHEAT GERM OIL (UNII: 14C97E680P)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:37945-874- 11	1 in 1 BOX	10/22/2014	09/01/2021		
1		30 mL in 1 BOTTLE; 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	10/22/2014			

Labeler - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

Establishment						
Name	Address	ID/FEI	Business Operations			
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-874)			

Revised: 12/2022 Bio-Medical & Pharmaceutical Manufacturing Corporation