NATURAL PEELING TRIACTIVE ACNE- salicylic acid lotion Casmara Cosmetics, SA

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.

Natural Peeling Tri Active. Acne treatment lotion

Stop use and ask a doctor if rash occurs

Children under 6 months: ask a doctor

. keep out of reach of children

Questions or Comments?

Questions or comments? + 34 961 501 099 M-F 9:00 am to 5:00 pm

. keep the product in a cool and dry place

Directions

- . clean the skin thoroughly before applying this product
- . cover the entire affected area with a thin layer one to three times daily, massage the area and rinse thoroughly.
- . because excessive dryness 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
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Uses

- . helps keep the skin clear of new blakcheads
- . acne treatment lotion
- . helps the skin clear of new blackheads

Active Ingredients

Salicylic acid 0.5%..... Acne Treatment

For external use only.

Do not use on damaged or broken skin.

Avoid use around the eyes

Do not sunbathe after application

Stop use and ask a doctor if rash occurs.

Children under 6 months: as a doctor.

KEEP OUT OF THE REACH OF CHILDREN

USING OTHER TOPICAL ACNE DRUGS AT THE SAME TIME OR INMEDIATELY FOLLOWING THE USE OF THIS PRODUCT MAY INCREASE DRYNESS OR IRRITATION OF THE SKIN. IF THIS OCCURS, ONLY ONE MEDICATION SHOULD BE USED UNLESS DIRECTED BY A DOCTOR

Sensitive Test for a New User

Apply product sparingly to one or two small affected areas during the first three days. If not discomfort occurs follow the directions state above in this label.

water, propylene glycol, glycolic acid, sodium hydroxide, lactic acid, carbomer 934, fragrance.

Drug Facts

Active ingredients

Purpose

Salicylic acid 0.5 % Acne treatment

Uses

· Helps keep the skin clear of new blackheads.

Warnings

For external use only.

Do not use on damaged or broken skin.

Avoid use around the eyes.

Do not sunbathe after application.

Stop use and ask a doctor if rash occurs.

Children under 6 months: ask a doctor.

Keep out of reach of children.

Using another topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs only one medication should be used unless directed by the doctor.

"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 on this label.

Directions

- \cdot Clean the skin thoroughly before applying this product.
- · Cover the entire affected area with a thin layer one to three times daily, massage the area and rinse thoroughly .

 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.

Other information

· keep the product in a cool and dry place.

Inactive ingredients

water, propylene glycol, glycolic acid, sodium hydroxide, lactic acid, carbomer 934, fragrance.

Questions or comments?

- +34 961 501 999 M-F 9:00 am to 5:00 pm

MADE IN SPAIN (EU)

CASMARA COSMETICS, S.A. High Quality Professional Dermocosmetic Laboratory

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Natural Peeling Tri Active
Acne Treatment Lotion
Intelligent Technology
Rgnerin Three Action Cleaner
Facial Collection



NATURAL PEELING

TRI-ACTIVE

PEELING NATUREL

TRI-ACTIVE



ACNE TREATMENT LOTION

Intelligent Technology

RGnerín Three Action Cleanser

500 ml **e** 16.9 fl.oz.

NATURAL PEELING TRIACTIVE ACNE

salicylic acid lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20151-077	
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 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)	48.5 mg in 1 mL			
PERFLUNAFENE (UNII: 54A06VV62N)	0.1 mg in 1 mL			
CARBOMER 934 (UNII: Z135WT9208)	1.5 mg in 1 mL			
PROPANEDIOL (UNII: 5965N8W85T)	40 mg in 1 mL			
GLYCOLIC ACID (UNII: 0WT12SX38S)	5.6 mg in 1 mL			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	2 mg in 1 mL			
LACTIC ACID (UNII: 33X04XA5AT)	1.8 mg in 1 mL			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:20151-077- 01	$500\ mL$ in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/04/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	07/03/2016		

Labeler - Casmara Cosmetics, SA (464973544)

Registrant - Casmara Cosmetics, SA (464973544)

Establishment					
Name	Address	ID/FEI	Business Operations		
Casmara Cosmetics, SA		464973544	manufacture (20 151-077)		

Revised: 11/2016 Casmara Cosmetics, SA