

CICATRIX SKIN PROTECTANT- glycerin cream
Catalysis, SL

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.

Cicatrix

ACTIVE INGREDIENTS PURPOSE
Glycerin 3%..... Skin Protectant

Tube_CICATRIX_Crema_30ml_USA_v.5

The image shows the packaging for Cicatrix Cream Skin Protectant. On the left, the brand name 'cicatrix' is written vertically in a large, stylized font, with 'CREAM Skin protectant' written vertically in a smaller font to its right. Below this, the volume 'e 30 ml • 1 fl.oz.' is printed. On the right side of the packaging, there is a 'DRUG FACTS' table and a block of text containing import and contact information.

DRUG FACTS	
Active Ingredient	Purpose
Cicatrix 3%.....	Skin protectant
Uses	
Helps to reduce the scars and marks in the skin	
Warnings	
For external use only Do not use on damaged or broken skin Stop use and ask a doctor if rash occurs Keep out of reach of children	
When using this product	
- Avoid contact with eyes Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center immediately.	
Directions	
- Clean and dry the affected area. Apply the product and massage the affected area. Following the instructions of the insert. Apply at least twice a day	
Other information	
- Keep the product in a cool and dry place	
Inactive Ingredients: Aqua, cyclopentasiloxane, cetyl alcohol, PEG-11 Stearyl Ether, steareth-2, Cetamide NP, Phosphatidylcholine, Cholesterol, Sodium Lauryl Lactylate, Cetearyl Alcohol, Stearic Acid, Cetearyl Alcohol, Stearic Acid, Salicylic Acid, Phenoxethanol, Ethylhexylglycerin, C12-C15 Alkyl Benzoate, steareth-20, Pinus Sylvestris (Bull) Extract, Sodium Benzoate, Potassium Sorbate, Sodium Hydroxide, Oxopropyl Sulfate, Perfume	
QUESTIONS OR COMMENTS ?:	
+34 912464602 Monday to Friday: 9:00 am to 5:00 pm (UTC/GMT +1)	

Imported by: GUNA, Inc.
3724 Crescent Court West -
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catalysis
Catalysis, S.L.
Macarena, 14 • 28016 Madrid
ESPAÑA / SPAIN
FABRICADO EN ESPAÑA

Warnings

For external use only.

Do not use on damaged or broken skin.

When using this product keep out of the eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children

Children under 6 months: ask a doctor.

WARNINGS

Stop use and ask a doctor if rash occurs

Children under 6 months: ask a doctor

Warnings

Keep out of reach of children

Questions or comments?

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

Other Information

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Directions

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. apply the product and massage the affected area

. follow the instructions on the insert

. apply at least twice a day

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Uses

. helps to reduce the scars and marks in t he skin

Inactive Ingredients

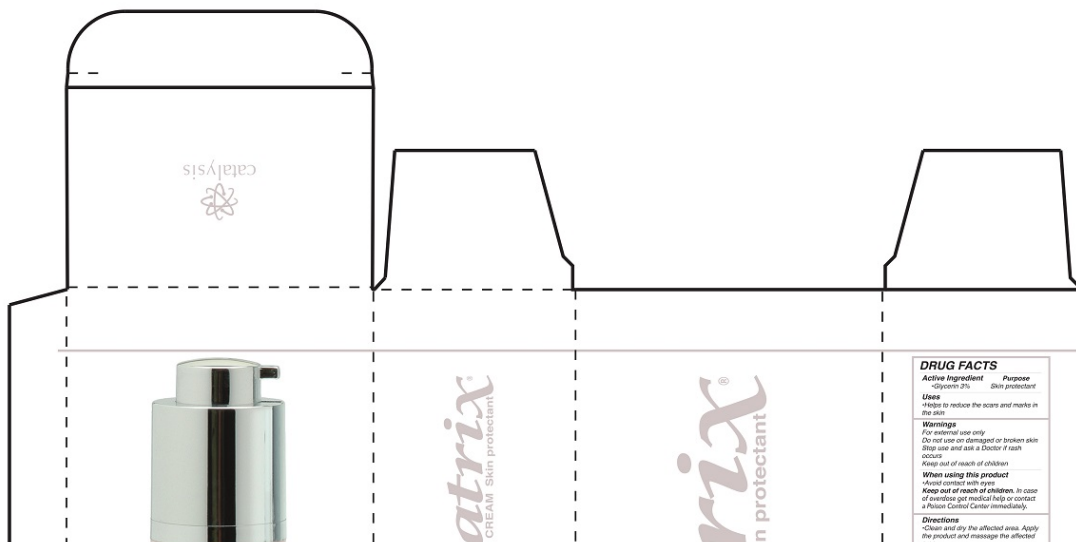
Aqua, Cyclopentasiloxane, Cetearyl Alcohol, PPG-11 Stearyl Ether, Steareth-2, Ceramide 3, Ceramide 6II, Ceramide 1, Phytosphingosine, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Centella Asiatica Leaf Extract, Maltodextrin, Stearic Acid, Palmitic Acid, Phenoxyethanol, Ethylhexylglycerin, C12-C15 Alkyl Benzoate, Steareth-20, Pinus Sylvestris Bud Extract, Sodium Benzoate, Potassium Sorbate, Sodium Hyaluronate, Carbomer, Diazolydinil Urea, Parfum(coumarin, hexyl cinnamal,linalool,d-limonene/dipentene/l-limonene,Geraniol,hydroxycitronellal), Sodium Hydroxide

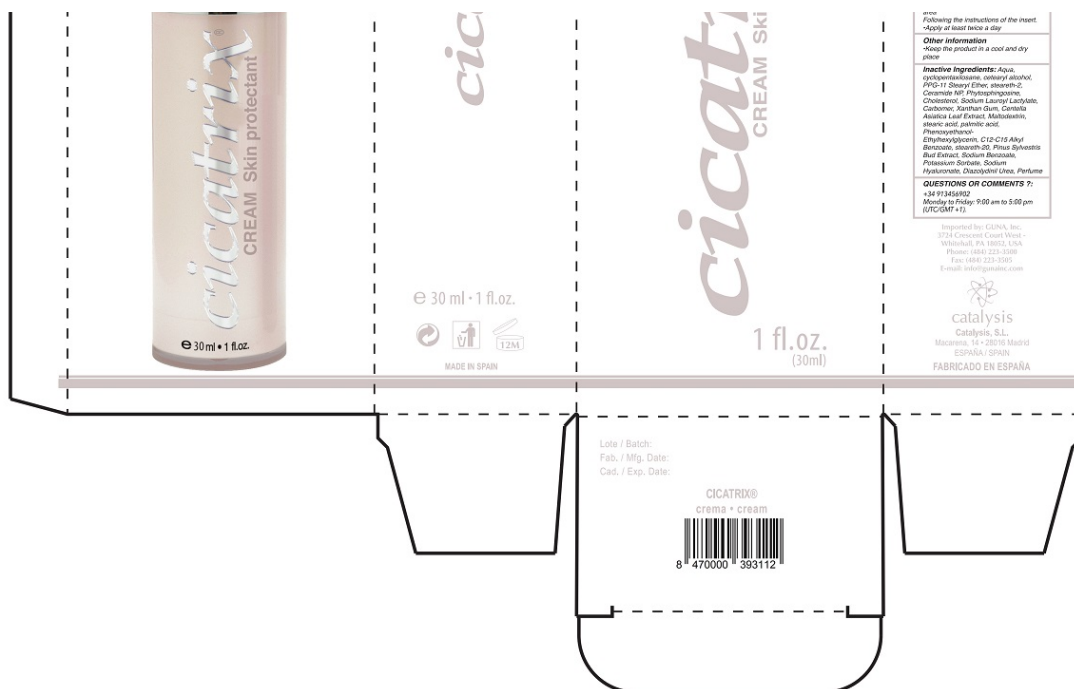
Uses

- helps to reduce the scars and marks in t he skin

Package Label

Caja_CICATRIX_Crema_30ml_USA_v.5





CICATRIX SKIN PROTECTANT

glycerin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COUMARIN (UNII: A4VZ22K1WT)	0.1 mg in 1 mL
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	0.2 mg in 1 mL
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	0.12 mg in 1 mL
PINE NEEDLE OIL (PINUS SYLVESTRIS) (UNII: 5EXL5H740Y)	0.12 mg in 1 mL
PPG-11 STEARYL ETHER (UNII: S4G2J0Y0LG)	3 mg in 1 mL
STEARETH-2 (UNII: V56DFE46J5)	2.4 mg in 1 mL
CERAMIDE 3 (UNII: 4370DF050B)	0.25 mg in 1 mL
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.25 mg in 1 mL
CERAMIDE 6 II (UNII: F1X8L2B00J)	0.25 mg in 1 mL
CHOLESTEROL (UNII: 97C5T2UQ7J)	0.25 mg in 1 mL

SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	0.25 mg in 1 mL
WATER (UNII: 059QF0K00R)	100 mg in 1 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	0.45 mg in 1 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.25 mg in 1 mL
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	3 mg in 1 mL
CENTELLA ASIATICA LEAF (UNII: 6810070TYD)	0.5 mg in 1 mL
STEARIC ACID (UNII: 4ELV7Z65AP)	0.5 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.5 mg in 1 mL
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	0.8 mg in 1 mL
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.07 mg in 1 mL
STEARETH-20 (UNII: L0Q8IK9E08)	0.6 mg in 1 mL
SODIUM BENZOATE (UNII: OJ245FE5EU)	0.14 mg in 1 mL
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	7 mg in 1 mL
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	0.2 mg in 1 mL
MALTODEXTRIN (UNII: 7CVR7L4A2D)	0.5 mg in 1 mL
PALMITIC ACID (UNII: 2V16EO95HI)	0.5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64539-006-02	1 in 1 BOX	05/02/2017	
1	NDC:64539-006-01	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	05/02/2017	

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

Name	Address	ID/FEI	Business Operations
Catalysis, SL		862795119	manufacture(64539-006)

Revised: 6/2017

Catalysis, SL