

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_50ml_USA_v.5

cicatrix[®]
CREAM Skin protectant

DRUG FACTS	
Active Ingredient	Purpose
-Glycerin 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, cetearyl alcohol, PEG-11 Stearyl Ether, steareth-2, Ceramide NP, Phytosphingosine, Cholesterol, Sodium Lauryl Lactylate, Carbomer, Xanthan Gum, Gentiana Asiatica Leaf Extract, Maltodextrin, stearic acid, palmitic acid, Phenoxethylalcohol, Ethylhexylglycerin, C12-C15 Alkyl Benzoate, steareth-20, Pinus Sylvestris Bud Extract, Sodium Benzoate, Potassium Sorbate, Sodium Hyaluronate, Diazolidinyl Urea, Perfume	
QUESTIONS OR COMMENTS ?: +34 913456902 Monday to Friday: 9:00 am to 5:00 pm (UTC+GMT +1).	



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catalysis
Catalysis, S.L.
Macarena, 14 • 28016 Madrid
ESPAÑA / SPAIN
FABRICADO EN ESPAÑA

e 50 ml • 1.7 fl.oz.

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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Uses

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

Inactive Ingredients

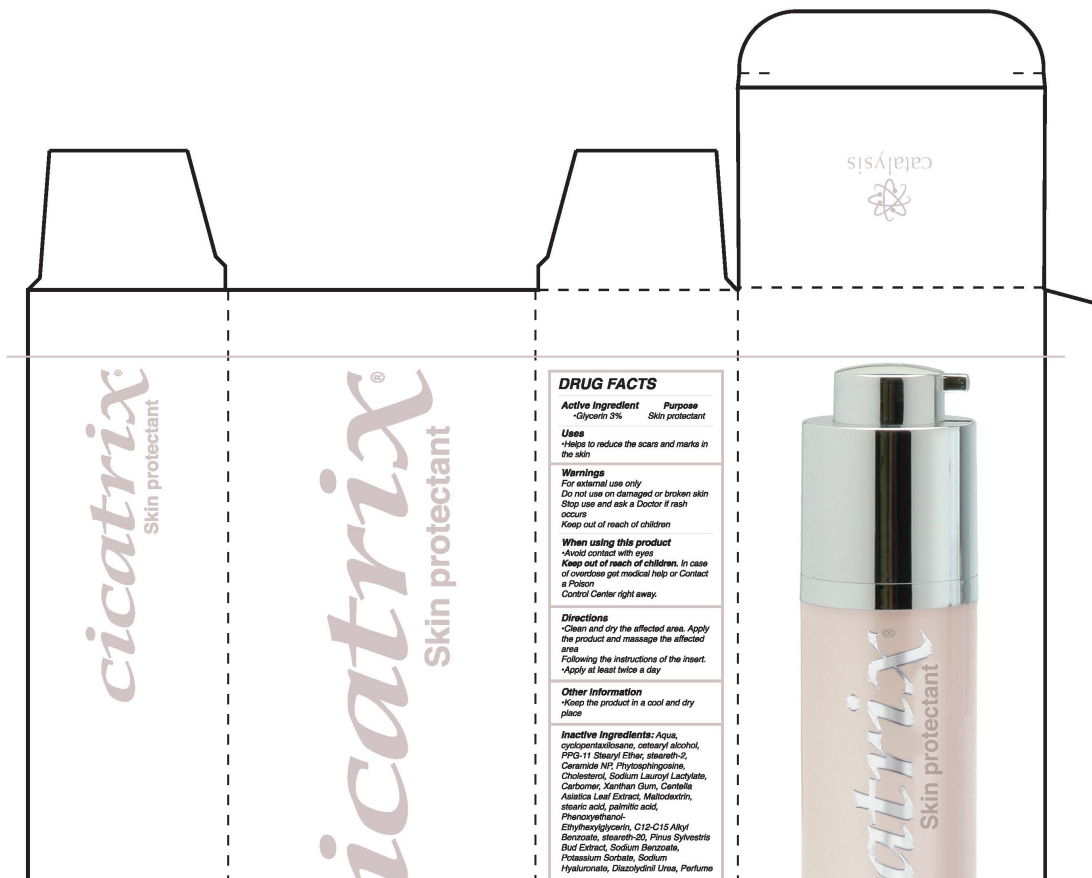
Aqua, Cyclopentasiloxane, Cetearyl Alcohol, PPG-11 Stearyl Ether, Steareth-2, Ceramide 3, Ceramide 6II, Ceramide 1, Phytosphingosine, Cholesterol, Sodium Lauroyl Lactylate, Carbomer, Xanthan Gum, Centella Asiatica Leaf Extract, Maltodextrin, Stearic Acid, Palmitic Acid, Phenoxyethanol, Ethylhexylglycerin, 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

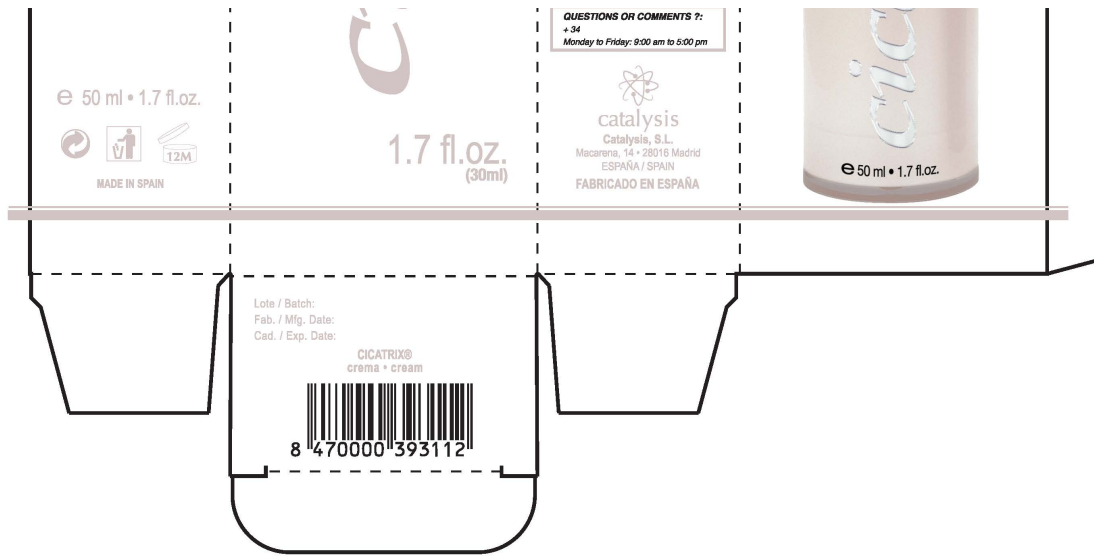
Uses

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

Package Label

Caja_CICATRIX_Crema_50ml_USA_v.1





TROQUEL CICATRIX / 50

CICATRIX SKIN PROTECTANT

glycerin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64539-005
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: 5EXL5H740 Y)	0.12 mg in 1 mL
PPG-11 STEARYL ETHER (UNII: S4G2J0 Y0LG)	3 mg in 1 mL
STEARETH-2 (UNII: V56DFE46J5)	2.4 mg in 1 mL
CERAMIDE 3 (UNII: 4370DF050 B)	0.25 mg in 1 mL
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	0.25 mg in 1 mL
CERAMIDE 6 II (UNII: F1X8L2B00 J)	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: 059QF0KO0R)	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:64539-005-02	1 in 1 BOX	05/02/2017	
1	NDC:64539-005-01	50 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(64539-005)

Revised: 6/2017

Catalysis, SL