

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

|  <p>e 30 ml • 1 fl.oz.</p> | <p>DRUG FACTS</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Cicatrix 3%</td> <td>Skin protectant</td> </tr> <tr> <th>Uses</th> <td> <ul style="list-style-type: none"> Helps to reduce the scars and marks in the skin </td> </tr> <tr> <th>Warnings</th> <td> <ul style="list-style-type: none"> 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 </td> </tr> <tr> <th>When using this product</th> <td> <ul style="list-style-type: none"> Avoid contact with eyes Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center immediately. </td> </tr> <tr> <th>Directions</th> <td> <ul style="list-style-type: none"> Clean and dry the affected area. Apply the product and massage the affected area Following the instructions of the insert. 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Macarena, 14 • 28016 Madrid ESPAÑA / SPAIN FABRICADO EN ESPAÑA</p> |
|---|--|-------------------|---------|-------------|-----------------|------|---|----------|--|-------------------------|--|------------|---|-------------------|--|-----------------------|--|--------------------------|--|---|
| Active ingredient | Purpose | | | | | | | | | | | | | | | | | | | |
| Cicatrix 3% | Skin protectant | | | | | | | | | | | | | | | | | | | |
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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

. keep the product in a cool and dry place

Directions

. clean and dry the affected area.

. apply the product and massage the affected area

. follow the instructions on the insert

. apply at least twice a day

- clean and dry the affected area.
- apply the product and massage the affected area
- follow the instructions on the insert
- apply at least twice a day

Uses

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

Prospecto Cicatrix Crema USA V.2



What is CICATRIX®?

CICATRIX® is a specific cream made from natural ingredients that helps to reduce the scars.

The active ingredients of CICATRIX® are Centella asiatica and Pinus sylvestris. Centella asiatica promotes and accelerates skin recovery. On the one hand, it acts by incorporating into and binding to collagen two amino acids - alanine and proline - fundamental for the biosynthesis of structural proteins, thus stimulating the formation of granulation tissue.

What is a scar?

A scar is the final result of the healing process of an injury. The new tissue formed (scar tissue) is weaker, less elastic, less vascularized, and a little more pigmented than the original tissue. Moreover, it can have aesthetic and functional effects on the person.

How should CICATRIX® be used?

Cleanse and dry the affected area. Apply a thin layer of CICATRIX® and massage the affected area following the instructions on this insert. The application and the massage should be carried out at least twice a day and for a minimum of one month or until the complete disappearance of the scar.

INGREDIENTS (INCI)

Aqua, cyclopentasiloxane, Cetearyl alcohol, PPG-11 Stearyl Ether, steareth-2, Ceramide NP, Phytosphingosine, Cholesterol, Sodium Lauryl 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, Diazolydinil Urea, Parfum.

PRECAUTIONS

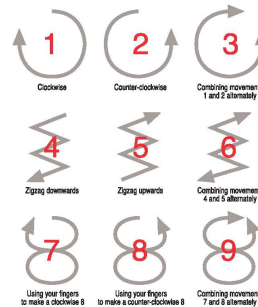
- For external use only
- Avoid contact with eyes
- Do not use on damaged or broken skin
- Stop use and ask a Doctor if rash occurs
- If swallowed get medical help or contact a Poison Control Center right away
- Keep out of the reach of children

PRESENTATION

1 fl.oz. and 1.7 fl.oz. containers

MASSAGE with CICATRIX®

Each one of the nine massage movements should be repeated 10 times on the affected area.



To end the massage, apply again a thin layer of CICATRIX® and use your fingers to make some feather-light strokes on the area near the affected area. (These feather-light strokes produce a vibration that facilitates the absorption of the cream.)



MADE IN SPAIN

Catalysis, S.L. • Macarona, 14 • 28016 Madrid • SPAIN

Package Label

Caia CICATRIX Crema 30ml USA v5



cicatrix
CREAM Skin protectant

cicatrix
CREAM Skin protectant

e 30 ml • 1 fl.oz.



MADE IN SPAIN

1 fl.oz.
(30ml)

DRUG FACTS

Active ingredient:
-Zinc Oxide 3%

Purpose:
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 an accident get medical help or contact a Poison Control Center immediately.

Directions:
-Clean and dry the affected area. Apply the product and reapply 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.

Active Ingredients: Aqua, cyclopentasiloxane, octyloxy alcohol, PEG-10 Stearyl Ether, stearyl alcohol, Cetearyl NF, Phytosteryl/PPG-19/18 Steareth-17, Cholesterol, Sodium Lauryl Sulfonate, Carbomer, Xanthan Gum, Ceramide Aliphica Leaf Extract, Maltodextrin, Stearic acid, parvitic acid, Phenylpropanediol, Ethylhexylglycerin, C12-C15 Alkyl Benzoate, isopropyl alcohol, Bisulfito de Sodio, Parfum, Polysiloxano, Sulfato de Sodio, Hidrolato, Diazolololil Urea, Perfume

QUESTIONS OR COMMENTS ?
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(UTC+01:00)

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glycerin cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:64539-015 |
| 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: 0A5MM307FC) | 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: 0TH5PC10R) | 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: 2V16EO95H1) | 0.5 mg in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:64539-015-02 | 1 in 1 BOX | 03/03/2018 | |

| | | | | |
|---|------------------|--|--|--|
| 1 | NDC:64539-015-01 | 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 | 03/03/2018 | |

Labeler - Catalysis, SL (862795119)

Registrant - Catalysis, SL (862795119)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------|---------|-----------|------------------------|
| Catalysis, SL | | 862795119 | manufacture(64539-015) |

Revised: 3/2018

Catalysis, SL