

FIXMYSKIN HEALING BALM FRAGRANCE-FREE- hydrocortisone ointment
Lovely Skin, Inc.

FixMySkin Healing Balm Fragrance-Free

Active Ingredient & Purpose

Active Ingredient	Purpose Hydrocortisone
1%	Antipruritic, External Analgesic

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, psoriasis, seborrheic dermatitis, insect bites, poison oak, or poison sumac, soaps, detergents, cosmetics, and jewelry, and for external genital and feminine itching, and external analgesic. Other uses of this product should only be under the advice and supervision of a doctor.

Warnings

For external use only. Avoid contact with eyes.

Stop use

and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Any use of this product other than those listed above should be under the advice and supervision of a doctor.

Do not use

for the treatment of diaper rash. Consult a doctor.

Keep out of reach of children

Keep out of reach of children

Directions

For itching associated with skin irritation, inflammation and rashes: Adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily. Children under 2 years of age: do not use - consult a doctor.

Inactive Ingredients

Ricinus Communis (Castor) Seed Oil, Stearyl Alcohol, C12-15 Alkyl Benzoate, Meadow Foam (Limnanthes Alba) Seed Oil, Shea Butter (Butyrospermum Parkii) Extract, Beeswax, Glycine Soja (Soybean) Germ Extract, Zea Mays (Corn) Starch, Silica, Theobroma Cacao (Cocoa) Seed Butter.

Questions or Comments?

www.FixMySkin.com Info@FixMySkin.com (402)697-1100

Description

Formulated by a board-certified dermatologist and his son. Dr. Joel Schlessinger and his son, Daniel Schlessinger, embarked on a five year quest to find the best balm product in a stick formulation for dry skin and irritation. After 54 different formulas, they finally came up with this patent pending formula. It is great for dry skin and helps improve the signs and symptoms of dry skin due to eczema, medications, psoriasis and other dry skin conditions. It is also available in the LovelySkin line without hydrocortisone (www.LovelySkin.com/Balm). Visit www.FixMySkin.com/Story for the whole story on how this product was developed.

Purpose

Antipruritic, External Analgesic

**FixMySkin Healing Balm Fragrance-Free 0.25oz/7.39ml (76314-002-02) |
FixMySkin Healing Balm Fragrance-Free 0.50oz/14.78ml (76314-002-03)
Representative Labeling**

FixMySkin®

HEALING BALM

Contains 1% Hydrocortisone Anti-Itch
Fragrance-Free

Great for chapped lips, cuticles,
finger cracks, irritated, cracked
and dry skin, psoriasis,
seborrheic dermatitis,
eczema, poison ivy
and insect bites!
Patent Pending

Dermatologist-Developed



Send your before
and after pictures to
pics@FixMySkin.com
to be entered
into a contest!

Net Wt. 0.25 fl oz. (7.39 ml)

FixMySkin®

Dermatologist-Developed

HEALING BALM

Contains 1% Hydrocortisone
Fragrance-Free

NFH

0.25 fl oz. (7.39 ml)

Great for chapped lips, irritated, cracked and dry
skin, seborrheic dermatitis, psoriasis, eczema,
poison ivy and insect bites!

Directions: Apply no more than 3-4 times daily. Discontinue if irritation occurs.

Active Ingredients: 1% Hydrocortisone

Manufactured in U.S.A. by Topical Pharmaceuticals, Inc.

Distributed by FixMySkin - 2929 Oak View Drive, Omaha, NE 68144

www.FixMySkin.com

NDC 76314-002-02

Drug Facts

Active Ingredient

Hydrocortisone 1% Antipruritic,
External Analgesic

Uses

For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, psoriasis, seborrheic dermatitis, insect bites, poison ivy, poison oak, or poison sumac, soaps, detergents, cosmetics, and jewelry, and for external genital itching, and feminine itching. Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

For external use only. Avoid contact with the eyes. Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days. Any use of this product other than those listed above should be under the advice and supervision of a doctor. Do not use for the treatment of diaper rash. Consult a doctor. Keep out of reach of children.

Directions

For itching associated with skin irritation, inflammation, and rashes:

- Adults and children 2 years of age and older: apply to the affected area not more than 3 to 4 times daily.
- Children under 2 years of age: do not use - consult a doctor.

Inactive Ingredients Ricinus Communis (Castor) Seed Oil, Stearyl Alcohol, C12-15 Alkyl Benzoate, Meadow Foam (Limnanthes Alba) Seed Oil, Shea Butter (Butyrospermum Parkii) Extract, Beeswax, Glycine Soja (Soybean) Germ Extract, Zea Mays (Corn) Starch, Silica, Theobroma Cacao (Cocoa) Seed Butter.

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LOT:

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by Topical Pharmaceuticals, Inc.
Distributed by FixMySkin
2929 Oak View Drive, Omaha, NE 68144

Patent Pending NFH
NDC 76314-002-02

FIXMYSKIN HEALING BALM FRAGRANCE-FREE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76314-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)	
SHEANUT OIL (UNII: O88E196QRF)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SOYBEAN (UNII: L7HT8F1ZOD)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCOA BUTTER (UNII: 512OYT1CRR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76314-002-03	14.78 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/17/2011	
2	NDC:76314-002-02	7.39 mL in 1 PACKAGE; Type 0: Not a Combination Product	12/31/2009	12/31/2009

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/31/2009	

Labeler - Lovely Skin, Inc. (968605571)

Registrant - Lovely Skin, Inc. (968605571)

Establishment

Name	Address	ID/FEI	Business Operations
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Topical Pharmaceuticals Inc.		831530683	manufacture(76314-002)
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Revised: 11/2023

Lovely Skin, Inc.