

FIXMYSKIN HEALING BALM VANILLA FLAVOR- hydrocortisone ointment
Lovely Skin, Inc.

FixMySkin Healing Balm Vanilla Flavor

Active Ingredient & Purpose

Active Ingredient	Purpose
1% Hydrocortisone	Hydrocortisone
Antipruritic	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, Vanilla Flavor.

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 Vanilla Flavor 0.15oz/4.43ml (76314-004-01)
Representative Labeling



**1% Hydrocortisone Anti-Itch
HEALING LIP BALM**

Vanilla flavor | Dermatologist-developed

**Treats and soothes dry, cracked
skin or lips, insect bites, eczema,
psoriasis and poison ivy.**

Net Wt. 0.15 oz. (4.25g)

FH

Costs less than prescription medications!

Visit [FixMySkin.com](https://www.FixMySkin.com) for more information.



Recyclable
Materials



NDC 76314-004-01

Drug Facts

Active ingredient

Hydrocortisone 1% Anti-itch, External Analgesic

Purpose

Use ■ For the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis and psoriasis, and for external genital 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

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

Inactive ingredients BEESWAX, C12-15 ALKYL BENZOATE, CASTOR SEED OIL (RICINUS COMMUNIS), COCOA SEED BUTTER (THEOBROMA CACAO), CORN STARCH (ZEA MAYS), MEADOW FOAM SEED OIL (LIMNANTHES ALBA), SHEA BUTTER EXTRACT (BUTYROSPERMUM PARKII), SILICA, SOYBEAN GERM EXTRACT (GLYCINE SOJA), STEARYL ALCOHOL, VANILLA FLAVOR.

Treats and soothes dry, cracked skin or lips, insect bites, eczema, psoriasis and poison ivy.



1% Hydrocortisone HEALING LIP BALM

Vanilla flavor | Dermatologist-developed

Directions: Apply 3-4 times daily. FH
Discontinue if irritation occurs.

**This product is packaged in outer box.
Please see outer box for Drug Facts.**

Manufactured by Topical Pharmaceuticals, Inc.
for Olive & Delmar, LLC.

NDC 76314-004-01 | U.S. Patent No. 8,685,381

www.FixMySkin.com

LOT:

0.15 oz. (4.25g)

FIXMYSKIN HEALING BALM VANILLA FLAVOR

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76314-004
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)				
VANILLA (UNII: Q74T35078H)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76314-004-01	4.43 mL in 1 PACKAGE; Type 0: Not a Combination Product	11/17/2011	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	11/17/2011	

Labeler - Lovely Skin, Inc. (968605571)

Registrant - Lovely Skin, Inc. (968605571)

Establishment			
Name	Address	ID/FEI	Business Operations
Topical Pharmaceuticals Inc.		831530683	manufacture(76314-004)