

**FIXMYSKIN HEALING BALM UNFLAVORED- hydrocortisone ointment**  
**Lovely Skin, Inc.**

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**FixMySkin Healing Balm Unflavored**

**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](http://www.FixMySkin.com)    [Info@FixMySkin.com](mailto: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](http://www.LovelySkin.com/Balm)). Visit [www.FixMySkin.com/Story](http://www.FixMySkin.com/Story) for the whole story on how this product was developed.

## **Purpose**

Antipruritic, External Analgesic

**FixMySkin Healing Balm Unflavored 0.15oz/4.43ml (76314-003-01)**  
**Representative Labeling**



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

Unflavored | Dermatologist-developed

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

Net Wt. 0.15 oz. (4.25g)

NFH

**Costs less than prescription medications!**

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

NDC 76314-002-01

## Drug Facts

### Active ingredient

Hydrocortisone 1% .....

### Purpose

Anti-itch, External Analgesic

**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.

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



**1% Hydrocortisone**  
**HEALING LIP BALM**  
Unflavored | Dermatologist-developed

**Directions:** Apply 3-4 times daily. NFH  
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 76314-003-01 | U.S. Patent No. 8,685,381

[www.FixMySkin.com](http://www.FixMySkin.com)

**LOT:**

0.15 oz. (4.25g)

**FIXMYSKIN HEALING BALM UNFLAVORED**

hydrocortisone ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76314-003
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE</b> (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:76314-003-01	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(76314-003)

Revised: 11/2023

Lovely Skin, Inc.