

**ROVECTIN ANTI IRRITANT BARRIER REPAIR ULTRA- dimethicone cream  
SECOND FORMULA INC.**

*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.*

-----

**ACTIVE INGREDIENT**

ACTIVE INGREDIENT: DIMETHICONE 1.80%

**INACTIVE INGREDIENT**

INACTIVE INGREDIENTS:

WATER, CYCLOPENTASILOXANE, BUTYROSPERMUM PARKII (SHEA BUTTER), HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, NIACINAMIDE, GLYCERIN, SQUALANE, CETEARYL METHICONE, PHENOXYETHANOL, RICINUS COMMUNIS (CASTOR) SEED OIL, PERSEA GRATISSIMA (AVOCADO) OIL, OLIVE GLYCERIDES, HEXYLDECANOL, POLYSORBATE 60, LINOLEIC ACID, GLYCINE SOJA (SOYBEAN) STEROLS, PHOSPHOLIPIDS, ALOE BARBADENSIS LEAF JUICE, HYDROXYETHYLCELLULOSE, ETHYLHEXYLGLYCERIN, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, SODIUM PHYTATE, TOCOPHEROL, CERAMIDE 3, SODIUM HYDROXIDE, HAEMATOCOCCUS PLUVIALIS EXTRACT

**PURPOSE**

PURPOSE: SKIN PROTECTANT

**WARNINGS**

WARNINGS:

FOR EXTERNAL USE ONLY.

AVOID CONTACT WITH EYES.

STOP USE AND ASK A DOCTOR IF CONDITION WORNSENS.

DO NOT USE ON DEEP OR PUNCTURE WOUNDS.

KEEP OUT OF THE REACH OF CHILDREN.

**KEEP OUT OF REACH OF CHILDREN**

KEEP OUT OF REACH OF CHILDREN

**INDICATIONS AND USAGE**

Directions:

Apply to face, neck, hands, feet and body.

Use as often as necessary.

**DOSAGE AND ADMINISTRATION**

Directions:

Apply to face, neck, hands, feet and body.

Use as often as necessary.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



# ROVECTIN



## Anti-irritant Barrier Repair Ultra Cream

Intensive Formula  
Hyper-hydrating  
Soothing and Protecting

Contains  
no carcinogen, no paraben  
no fragrance, no colorant

3.4 fl oz

e 100 ml

ACTIVE INGREDIENTS:  
DIMETHICONE 1.80%

INACTIVE INGREDIENTS:  
WATER · CYCLOPENTASILOXANE · BUTYRDSPERMUM PARKII (SHEA BUTTER) · HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER · NIACINAMIDE · GLYCERIN · SQUALANE · CETEARYL METHICONE · PHENOCYETHANOL · RICINUS COMMUNIS (CASTOR) SEED OIL · PERSEA GRATISSIMA (AVOCADO) OIL · OLIVE GLYCERIDES · HEXYLDECANOL · POLYSORBATE 80 · LINOLEIC ACID · GLYCINE SOJA (SOYBEAN) STEROLS · PHOSPHOLIPIDS · ALOE BARBADENSIS LEAF JUICE · HYDROXYETHYLCELLULOSE · ETHYLHEXYLGLYCERIN · HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL · SODIUM PHYTATE · TOCOPHEROL · CERAMIDE 3 · SODIUM HYDROXIDE · HAEMATOCOCCUS PLUVIALIS EXTRACT

PURPOSE SKIN PROTECTANT

USES: PROTECTS AND HELPS RELIEVE CHAFED, CHAPPED, OR CRACKED SKIN.

WARNINGS: FOR EXTERNAL USE ONLY. AVOID CONTACT WITH EYES. STOP USE AND ASK A DOCTOR IF CONDITION WORSENS. DO NOT USE ON DEEP OR PUNCTURE WOUNDS. KEEP OUT OF THE REACH OF CHILDREN.

# ROVECTIN



Specially formulated to improve quality of life and tolerability from dry, sensitive and irritated skin conditions.

Skin Barrier Repair Complex replenishes the diminished essential barrier lipids with naturally derived plant extracts.

Directions: Apply to face, neck, hands, feet and body. Use as often as necessary.

- Provides immediate and lasting hydration.
- Delivers effective nutrients to the skin.
- Helps repair skin barrier to maintain skin's healthy hydro-balance. Non-comedogenic.
- Soothes and calms skin, leaving it velvet-soft to the touch. Not sticky or oily.

Dedicated to developing innovative products to help individuals dealing with skin-related side effects.

Composed from various beneficial botanicals to provide hyper-hydration for your skin.

Unique, not only because of the ingredients that it contains but also because of what it does not. Does not include carcinogen, paraben, fragrance or colorant, all of which are not appropriate for those with certain skin care issues.

## ROVECTIN

Anti-irritant Barrier Repair  
Ultra Cream



5 09348 500003

# ROVECTIN ANTI IRRITANT BARRIER REPAIR ULTRA

dimethicone cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52970-010
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O) (Dimethicone - UNII:92RU3N3Y1O)	Dimethicone	1.8 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Shea Butter</b> (UNII: K49155WL9Y)	
<b>Niacinamide</b> (UNII: 25X51I8RD4)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Squalane</b> (UNII: GW89575KF9)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52970-010-01	100 mL in 1 CARTON		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/01/2012	

**Labeler** - SECOND FORMULA INC. (557819411)

**Registrant** - SECOND FORMULA INC. (557819411)

## Establishment

Name	Address	ID/FEI	Business Operations
SECOND FORMULA INC.		557819411	manufacture(52970-010)