

PRIMEROSE EGF- niacinamide, dimethicone, adenosine cream

Royal Springs Cosmetics USA, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

PRIMEROSE EGF REPAIRING CREAM

Active ingredients

Niacinamide (2%)

Dimethicone (1.5%)

Adenosine (0.04%)

Purpose

skin protectant

Keep out of reach of children

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- Do not swallow. In case of accidental ingestion, seek professional assistance.

Uses

Skin brightening and wrinkle care. Keep skin soft and smooth.

Warnings

For external use only

Do not use when Your skin is red, inflamed, irritated or painful

When using this product

- Do not apply on other parts of the body

- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

- Do not apply directly to wound or open cut.

Stop use and ask doctor if rash or irritation on skin develops and lasts.

Store at room temperature

Directions

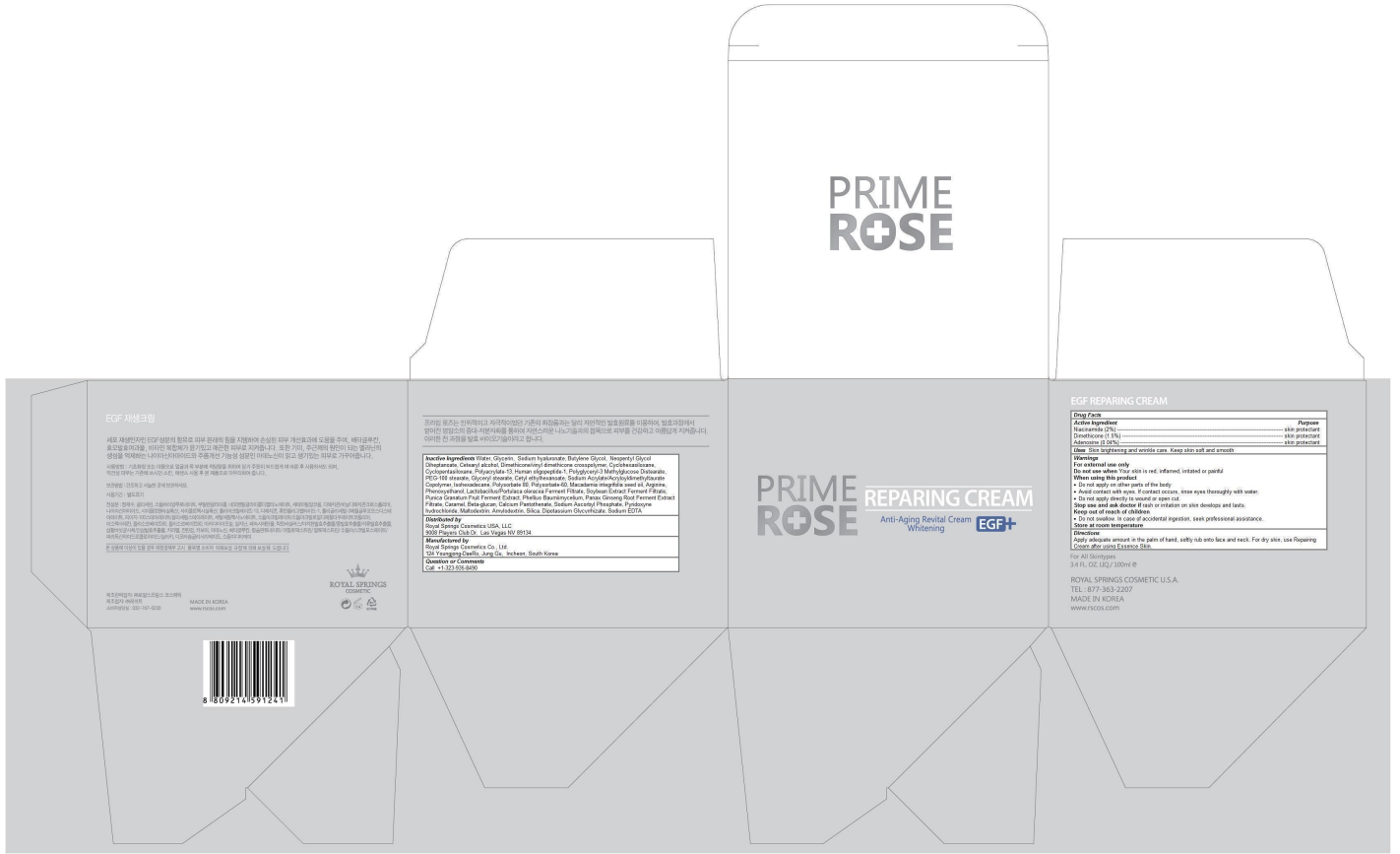
Apply adequate amount in the palm of hand, softly rub onto face and neck. For dry skin, use Repairing Cream after using Essence Skin.

Inactive ingredients

Water, Glycerin, Sodium hyaluronate, Butylene Glycol, Neopentyl Glycol Diheptanoate, Cetearyl alcohol, Dimethicone/vinyl dimethicone crosspolymer, Cyclohexasiloxane, Cyclopentasiloxane, Polyacrylate-13, Human oligopeptide-1, Polyglyceryl-3 Methylglucose Distearate, PEG-100 stearate, Glyceryl stearate, Cetyl ethylhexanoate, Sodium Acrylate/Acryloyldimethyltaurate Copolymer, Isohexadecane, Polysorbate 80, Polysorbate-60, Macadamia integrifolia seed oil, Arginine, Phenoxyethanol, Lactobacillus/Portulaca oleracea Ferment Filtrate, Soybean Extract Ferment Filtrate, Punica Granatum Fruit Ferment Extract, Phellius Baumiimycelium, Panax Ginseng Root Ferment Extract

Filtrate, Caramel, Beta-glucan, Calcium Pantothenate, Sodium Ascorbyl Phosphate, Pyridoxine hydrochloride, Maltodextrin, Amylodextrin, Silica, Dipotassium Glycyrrhizate, Sodium EDTA

PRIMEROSE EGF REPAIRING CREAM



PRIMEROSE EGF

niacinamide, dimethicone, adenosine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69888-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	0.02 in 100 mL
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	0.015 in 100 mL
ADENOSINE (UNII: K72T3FS567) (ADENOSINE - UNII:K72T3FS567)	ADENOSINE	0.0004 in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)
PEG-100 STEARATE (UNII: YD01N1999R)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)
ISOHEXADECANE (UNII: 918X10UF1E)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
POLYSORBATE 60 (UNII: CAL22UVI4M)
MACADAMIA OIL (UNII: 515610SU8C)
ARGININE (UNII: 94ZLA3W45F)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ASIAN GINSENG (UNII: CUQ3A77YXI)
POMEGRANATE (UNII: 56687D1Z4D)
CARAMEL (UNII: T9D99G2B1R)
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
AMYLOPECTIN (UNII: 4XO4QFV777)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
EDETATE SODIUM (UNII: MP1J8420LU)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69888-102-02	1 in 1 BOX	02/13/2018	
1	NDC:69888-102-01	100 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/13/2018	

Labeler - Royal Springs Cosmetics USA, LLC (079837692)

Registrant - Royal Springs Cosmetics USA, LLC (079837692)

Establishment

Name	Address	ID/FEI	Business Operations
Royal Springs Cosmetics USA, LLC		079837692	relabel(69888-102)

Establishment

Name	Address	ID/FEI	Business Operations
Royal Springs Cosmetic Co.,Ltd.		689514344	manufacture(69888-102)

Revised: 1/2019

Royal Springs Cosmetics USA, LLC