

**PURESKIN SEBORRHEIC DERMATITIS ECZEMA CREAM- seborrheic dermatitis
eczema cream cream
Stellans 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

Ketoconazole 0.5%

Purpose

seborrheic dermatitis, eczema

Use

USES for relief of skin itching, irritation, redness, flaking and scaling associated with seborrheic dermatitis, eczema, folliculitis, or psoriasis, and to help prevent symptom recurrence.

Warnings

For external use only.

Do not use

On open skin wounds
In children less than 6 months of age.

When Using

Avoid contact with eyes. If contact occurs, rinse the eyes immediately with water.
Keep out of the reach of young children.

Stop Use

Condition worsens or doesn't improve after regular use of the product as directed.
You become pregnant, or are planning to become pregnant, while using the product.

Ask Doctor

Condition worsens or doesn't improve after regular use of the product as directed.
You become pregnant, or are planning to become pregnant, while using the product.

Keep Out Of Reach Of Children

Keep out reach of children.

Directions

Clean the affected area with warm water and dry thoroughly.

Apply a thin layer over the affected area two to three times daily and gently massage it 2 minutes, repeat 3 to 5 days after symptoms disappear to control recurrence.

Children should use it under the supervision of adults.

Other information

store at 20-25 °C

Inactive ingredients

Glycerin, Sodium Hyaluronate, Salicylic Acid, Rhinacanthus Nasutus Leaf, Heba Violae, Euphorbia Hirta L., Murraya Exotica L., Mentha Canadensis L., Cortexdictamnii, Sophora Flavescens Root, Cnidium Monnieri (L.) Cusson, Smilax Glabra Rhizome, Mosla Cavaleriei H.Lv., Phellodendron Amurense Rupr., Fischereuphorbia Root, Gleditsia Sinensis Thorn, Kochia Scoparia, Chlorhexidine Acetate, Stemona Tuberosa Lour

Questions

info@pureskinsupport.com

www.pureskinsupport.com

PRINCIPAL DISPLAY PANEL

BENEFITS

- ✓ Fungal Protection
- ✓ Soothing & Relief
- ✓ Recurrence Control
- ✓ Skin Barrier Recovery

WARNINGS

- * For external use only.
- * Avoid contact with eyes. If contact occurs, rinse the eyes immediately with water.
- * Keep out of the reach of young children. If swallowed, get medical help immediately.

DO NOT USE

- On open skin wounds.
- In children less than 6 months of age.

QUESTIONS & COMMENTS

info@pureskinsupport.com www.pureskinsupport.com

pureskin

SEBORRHEIC DERMATITIS & ECZEMA

NATURAL RELIEF RECOVERY CREAM

Irritated Skin | Flaking Dandruff | Itchy Patches

3.4 fl. oz. (100 ml)

INGREDIENTS

Ketoconazole, Glycerin, Sodium Hyaluronate, Salicylic Acid, Rhinacanthus Nasutus Leaf, Heba Violae, Euphorbia Hirta L., Murraya Exotica L., Mentha Canadensis L., Cortexdictamnii, Sophora Flavescens Root, Cnidium Monnieri (L.) Cusson, Smilax Glabra Rhizome, Mosla Cavaleriei H.Lv., Phellodendron Amurense Rupr., Fischereuphorbia Root, Gleditsia Sinensis Thorn, Kochia Scoparia, Chlorhexidine Acetate, Stemona Tuberosa Lour.

DIRECTIONS

1. Clean the affected area with warm water and dry thoroughly.
2. Apply a thin layer over the affected area two to three times daily and gently massage it 2 minutes, repeat 3 to 5 days after symptoms disappear to control recurrence.
3. Children should use it under the supervision of adults.



PURESKIN SEBORRHEIC DERMATITIS ECZEMA CREAM

seborrheic dermatitis eczema cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83565-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)	KETOCONAZOLE	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
RHINACANTHUS NASUTUS LEAF (UNII: 970QD55S9I)	
DICTAMNUS DASYCARPUS ROOT (UNII: 6153LEN214)	
MOSLA CAVALERIEI WHOLE (UNII: 0508B640S2)	
GLEDITSIA SINENSIS THORN (UNII: 26LKE578NY)	
CHLORHEXIDINE ACETATE (UNII: 5908ZUF22Y)	

SALICYLIC ACID (UNII: O414PZ4LPZ)
EUPHORBIA HIRTA LEAF (UNII: 243K8QF0MS)
MURRAYA PANICULATA LEAFY TWIG (UNII: VO9X9681W9)
MENTHA CANADENSIS WHOLE (UNII: J1BO4MHT2L)
CNIDIUM MONNIERI WHOLE (UNII: GYR30735RE)
BASSIA SCOPARIA FRUIT (UNII: 04W97Z676Y)
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)
SMILAX GLABRA TUBER (UNII: PES3YXA3LR)
STEMONA TUBEROSA WHOLE (UNII: 9373ZOT316)
PHELLODENDRON AMURENSE WHOLE (UNII: 3OZN5NGR9L)
EUPHORBIA FISCHERIANA ROOT (UNII: R4DRG4762Y)
GLYCERIN (UNII: PDC6A3C0OX)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
VIOLA ADUNCA WHOLE (UNII: 26Z8E4RZ3Q)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83565-001-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M005	07/07/2023	

Labeler - Stellans Inc. (111157321)

Establishment

Name	Address	ID/FEI	Business Operations
Stellans Inc.		111157321	label(83565-001) , manufacture(83565-001)

Revised: 7/2023

Stellans Inc.