

**SEBORRHEIC DERMATITIS THERAPY- salicylic acid, pyrithione zinc cream
PSODEX USA INC**

Seborrheic Dermatitis Therapy Cream

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Allantoin, Ascorbic Acid, Benzoic Acid, a-Bisabolol, Cetyl Alcohol, Chloroxylenol, Dehydroacetic Acid, Di-C12-13 Alkyl Malate, Dipropylene Glycol, Distilled Water, Glyceryl Monostearate, Laureth-9, Mentha Piperita Extract, Octyldodecanol, Panthenol, Paraffinum Liquidum, Phenoxyethanol, Undecylenic Acid, Urea, Xanthan Gum, Zinc Oxide

Seborrheic Dermatitis is a chronic inflammatory skin condition that can fluctuate over time.

The main goal of treatment is to manage symptoms

PSODEX Seborrheic Dermatitis Therapy Cream offers a soothing formula that helps block the recurrence of Seborrheic Dermatitis symptoms with the help of SALICYLIC ACID and PYRITHIONE ZINC

PREVENTS:

Moisture loss and skin irritation

RELIEVES:

Itching, inflammation, and roughness

CONTROLS:

Flaking, scaling, eruption, and excessive sebum secretion

HELPS BLOCK:

Recurrence of Seborrheic Dermatitis symptoms

DISTRIBUTED BY: Psodex USA Inc.

9898 Bissonnet St Ste 625 Houston, TX 77036

1-844 4PSODEX www.psodexusa.com

MANUFACTURED FOR

Yesim Derma Laboratories

Active ingredient

Pyrrithone Zinc 1%

Salicylic Acid 1,5%

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Pyrithone Zinc 1%

Salicylic Acid 1,5%

Use

For the treatment of Seborrheic Dermatitis

Provides relief from the symptoms of Seborrheic Dermatitis, including itching, redness, and scaling of the skin.

Directions

Cleanse the skin thoroughly before applying the product

Apply to affected areas with a thin layer, one to three times daily or as directed by a doctor

Ask a doctor before use if

Condition covers a large area of the body

Stop use and ask a doctor if

Condition worsens or does not improve after regular use of this product as directed.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Do not use

On large or deep wounds

On damaged or irritated skin not caused by Seborrheic Dermatitis

When using this product

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

Other information

Store at controlled room temperature 59-86°F

Questions or Comments

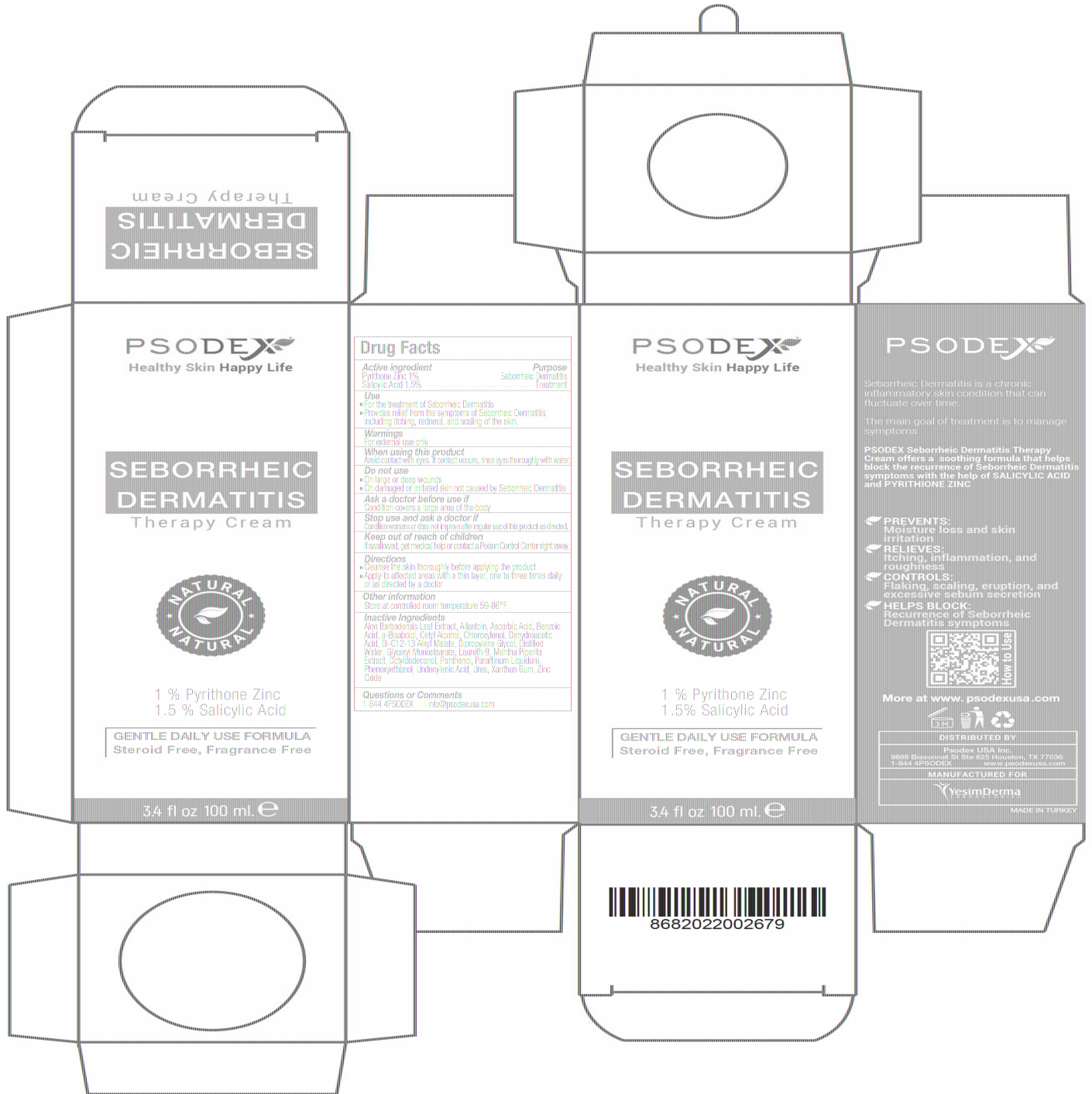
1 844 4PSODEX | info@psodexusa.com

Warnings

For external use only

Purpose

Seborrheic Dermatitis Treatment



SEBORRHEIC DERMATITIS THERAPY
salicylic acid, pyrithione zinc cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73503-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRITHIONE ZINC (UNII: R953O2RHZ5) (PYRITHIONE ZINC - UNII:R953O2RHZ5)	PYRITHIONE ZINC	1 g in 100 mL
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.2 g in 100 mL
UNDECYLENIC ACID (UNII: K3D86KJ24N)	2 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z)	9 g in 100 mL
ALLANTOIN (UNII: 344S277G0Z)	2 g in 100 mL
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	5 g in 100 mL
XANTHAN GUM (UNII: TTV12P4NEE)	0.3 g in 100 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	5 g in 100 mL
DI-C12-13 ALKYL MALATE (UNII: RRL7C51WPD)	2 g in 100 mL
OCTYLDODECANOL (UNII: 461N1O614Y)	2 g in 100 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.5 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	5 g in 100 mL
PANTHENOL (UNII: WW9CM0067Z)	1 g in 100 mL
MINERAL OIL (UNII: T5L8T28FGP)	5 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 g in 100 mL
UREA (UNII: 8W8T17847W)	5 g in 100 mL
LEVOMENOL (UNII: 24WE03BX2T)	2 g in 100 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	2 g in 100 mL
CHLOROXYLENOL (UNII: 0F32U78V2Q)	0.5 g in 100 mL
BENZOIC ACID (UNII: 8SKN0B0MIM)	0.25 g in 100 mL
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	0.25 g in 100 mL
WATER (UNII: 059QF0KO0R)	45 mL in 100 mL
POLIDOCANOL (UNII: 0AWH8BFG9A)	3 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73503-010-01	1000 in 1 BOX	01/01/2024	
1	NDC:73503-010-00	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M032	01/01/2024	

Labeler - PSODEX USA INC (076051073)

Registrant - PSODEX USA INC (076051073)

Establishment

Name	Address	ID/FEI	Business Operations
BERKO ILAC VE KIMYA SANAYI ANONIM SIRKETI-SULTANBEYLI SUBESI		533135007	manufacture(73503-010)

Revised: 12/2023

PSODEX USA INC