

**ROSACEA THERAPY MOISTURIZING- azelaic acid, tranexamic acid cream
PSODEX USA INC**

Rosacea Therapy Moisturizing Cream

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

The main goal of treatment is to manage symptoms

PSODEX Rosacea Therapy Moisturizing Cream offers a soothing formula that helps block the recurrence of Rosacea symptoms with the help of AZELAIC ACID and TRANEXAMIC ACID

PREVENTS:

Moisture loss and skin irritation

RELIEVES:

Itching, inflammation, and roughness

CONTROLS:

Flaking, scaling, eruption, and excessive sebum secretion

HELPS BLOCK:

Recurrence of rosacea symptoms

Rosacea Therapy Moisturizing Cream Active ingredient:

Active ingredient:

Azelaic Acid 5%
Tranexamic Acid 1%

Purpose:

Rosacea Treatment

Rosacea Therapy Moisturizing Cream

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Inactive Ingredients:

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

Rosacea Therapy Moisturizing Cream

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

Rosacea Therapy Moisturizing Cream

DISTRIBUTED BY: Psodex USA Inc.

9898 Bissonnet St Ste 625 Houston, TX 77036

1-844 4PSODEX www.psodexusa.com

MANUFACTURED FOR

Yesim Derma Laboratories

Rosacea Therapy Moisturizing Cream

Ask a doctor before use if : Condition covers a large area of the body

Rosacea Therapy Moisturizing Cream

Do not use:

On large or deep wounds

On damaged or irritated skin not caused by Rosacea

Rosacea Therapy Moisturizing Cream

Keep out of reach of children: If swallowed, get medical help or contact a Poison Control

Center right away.

Questions or Comments:

1 844 4PSODEX | info@psodexusa.com

Stop use and ask a doctor if

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

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

Warnings

For external use only

Use

Treats and controls symptoms of Rosacea
Reduces redness and inflammation associated with Rosacea
Promotes even skin tone
Minimizes the appearance of blood vessels

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ROSACEA THERAPY MOISTURIZING

azelaic acid, tranexamic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73503-009
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRANEXAMIC ACID (UNII: 6T84R30KC1) (TRANEXAMIC ACID - UNII:6T84R30KC1)	TRANEXAMIC ACID	1 g in 100 mL

AZELAIC ACID (UNII: F2VW3D43YT) (AZ ELAIC ACID - UNII:F2VW3D43YT)

AZELAIC ACID

5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALLANTOIN (UNII: 344S277G0Z)	2 g in 100 mL
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	0.25 g in 100 mL
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	5 g in 100 mL
MINERAL OIL (UNII: T5L8T28FGP)	5 g in 100 mL
POLIDOCANOL (UNII: 0AVH8BFG9A)	3 g in 100 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.5 g in 100 mL
OCTYLDODECANOL (UNII: 461N1O614Y)	2 g in 100 mL
ALOE VERA LEAF (UNII: ZY81Z83H0X)	5 g in 100 mL
DIPROPYLENE GLYCOL (UNII: E107L85C40)	0.2 g in 100 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	1 g in 100 mL
WATER (UNII: 059QF0KO0R)	43.5 mL in 100 mL
UREA (UNII: 8W8T17847W)	5 g in 100 mL
PANTHENOL (UNII: WW9CM0067Z)	1 g in 100 mL
LEVOMENOL (UNII: 24WE03BX2T)	2 g in 100 mL
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	2 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
ZINC OXIDE (UNII: SOI2LOH54Z)	9 g in 100 mL
BENZOIC ACID (UNII: 8SKN0B0MIM)	0.25 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73503-009-01	1000 in 1 BOX	01/01/2024	
1	NDC:73503-009-00	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	M006	01/01/2024	

Labeler - PSODEX USA INC (076051073)**Registrant** - PSODEX USA INC (076051073)