

15% AZELAIC ACID ACNE CREAM- 15% azelaic acid acne cream cream
Guangzhou Ariel Biotech Co., Ltd.

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.

84148-010

Active Ingredient(s)

AZELAIC ACID 15.00000%

HYDROXYETHYLPIPERAZINE ETHANE SULFONIC ACID 0.50000%

CAPRYLOYL GLYCINE 0.15000%

o-CYMEN-5-OL 0.09000%

MADECASSOSIDE 0.05500%

CENTELLA ASIATICA EXTRACT 0.03000%

LAVANDULA HYBRIDA OIL 0.03000%

ASIATICOSIDE 0.01500%

SAURURUS CHINENSIS LEAF/ROOT EXTRACT 0.01000%

TARAXACUM OFFICINALE (DANDELION) LEAF EXTRACT 0.01000%

STEPHANIA TETRANDRA EXTRACT 0.00160%

Purpose

Acne Cream

- ①Treatments for acne.
- ②Reduces acne and blemishes.
- ③Evens skin tone & fades spots.
- ④Balances oil & prevents breakouts.

Use

Use: Acne cream

Warnings

For external use only, avoid the eye area. Avoid direct sunlight during use. Discontinue use immediately if irritation occurs. Store in a cool, dry place.

Do not use

If there is any irritation, please stop using immediately

When Using Section: When using this product, avoid contact with eyes. If contact occurs, rinse thoroughly with water. Discontinue use if any irritation or adverse reaction occurs.

For external use only, avoid the eye area. Avoid direct sunlight during use. Discontinue use immediately if irritation occurs. Store in a cool, dry place.

Keep out of reach of children.

Directions

Apply a thin layer to cleansed face or affected areas morning and evening. Avoid the eye area. Use sunscreen during the day.

Other information

No Data

Inactive ingredients

INGREDIENTS: WATER, AZELAIC ACID, BUTYLENE GLYCOL, METHYLPROPANEDIOL, DIMETHICONE, CETEARYL GLUCOSIDE, DIPROPYLENE GLYCOL, SORBITAN OLIVATE, POLYACRYLATE-6, SQUALANE, CETYL ALCOHOL, HYDROXYPROPYL CYCLODEXTRIN, 1,2-HEXANEDIOL, 4-HYDROXYACETOPHENONE, HYDROXYETHYLPIPERAZINEETHANE SULFONIC ACID, STEARYL ALCOHOL, ALLANTOIN, CYCLODEXTRIN, CAPRYLOYL GLYCINE, XANTHAN GUM, O-CYMEN-5-OL, MADECASSOSIDE, CENTELLA ASIATICA EXTRACT, LAVANDULA ANGUSTIFOLIA OIL, CENTELLA ASIATICA, SAURURUS CHINENSIS LEAF/ROOT EXTRACT, TARAXACUM OFFICINALE LEAF EXTRACT, STEPHANIA TETRANDRAE EXTRACT

Package Label - Principal Display Panel

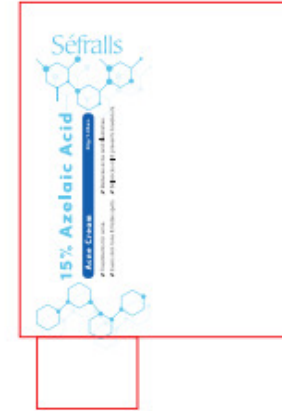
彩盒尺寸29.5*29.5*126.6
370g银卡，逆向



pantone 7455C

pantone 2985C

软管尺寸77*96



15% AZELAIC ACID ACNE CREAM

15% azelaic acid acne cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84148-010
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) (TARAXACUM OFFICINALE LEAF - UNII:0022LFJ74Y)	TARAXACUM OFFICINALE LEAF	0.01 g in 100 g
MADECASSOSIDE (UNII: CQ2F5O6YIY) (MADECASSOSIDE - UNII:CQ2F5O6YIY)	MADECASSOSIDE	0.055 g in 100 g
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J) (CENTELLA ASIATICA TRITERPENOIDS - UNII:4YS74Q4G4J)	CENTELLA ASIATICA TRITERPENOIDS	0.03 g in 100 g
LAVANDIN OIL (UNII: 9RES347CKG) (LAVANDIN OIL - UNII:9RES347CKG)	LAVANDIN OIL	0.03 g in 100 g
ASIATICOSIDE (UNII: PKO39VY215) (ASIATICOSIDE - UNII:PKO39VY215)	ASIATICOSIDE	0.015 g in 100 g
AZELAIC ACID (UNII: F2VW3D43YT) (AZ ELAIC ACID - UNII:F2VW3D43YT)	AZ ELAIC ACID	15 g in 100 g
O-CYMEN-5-OL (UNII: H41B6Q1I9L) (O-CYMEN-5-OL - UNII:H41B6Q1I9L)	O-CYMEN-5-OL	0.09 g in 100 g
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ) (CAPRYLOYL GLYCINE - UNII:8TY5YO42NJ)	CAPRYLOYL GLYCINE	0.15 g in 100 g
HYDROXYETHYLPIPERAZINE ETHANE SULFONIC ACID (UNII: RWW266YE9I)	HYDROXYETHYLPIPERAZINE	0.5 g

(HYDROXYETHYLPIPERAZINE ETHANE SULFONIC ACID - UNII:RWW266YE9I) ETHANE SULFONIC ACID in 100 g

Inactive Ingredients

Ingredient Name	Strength
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SQUALANE (UNII: GW89575KF9)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLODEXTRINS (UNII: 7E6SK9QDT8)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84148-010-01	30 g in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/23/2024	

Labeler - Guangzhou Ariel Biotech Co., Ltd. (402818771)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Ariel Biotech Co., Ltd.		402818771	manufacture(84148-010)

Revised: 9/2024

Guangzhou Ariel Biotech Co., Ltd.