

**10% AZELAIC ACID ACNE CREAM- 10% 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.

84148-009

Active Ingredient(s)

AZELAIC ACID 10.00000%

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 treatment

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

Use

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

Warnings

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

Stop using immediately if there is any stimulation

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

WATER, AZEL AIC ACID, BUTYLENE GLYCOL, METHYLPROPANEDIOL, DIMETHICONE, CETEARYL GLUCOSIDE, DIPROPYLENE GLYCOL, SORBITAN OLIVATE, POLYACRYLATE-6, SQUAL ANE, CETYL ALCOHOL, HYDROXYPROPYL CYCLODEXTRIN, 1,2-HEXANEDIOL, 4-HYDROXYACETOPHENONE, HYDROXYETHYLPYPERAZINEETHANE SULFONIC ACID, STEARYL ALCOHOL, ALLANTOIN, CYCLODEXTRIN, CAPRYLOYL GLYCINE, XANTHAN GUM, O-CYMEN-5-OL, MADECASSOSIDE, CENTELLA ASIATICA EXTRACT, LAVANDULA ANGUSTIFOLIA OL, CENTELLA ASIATICA, SAURURUS CHINENSIS LEAF/ROOT EXTRACT, TARAXACUM OFFICINALE LEAF EXTRACT, STEPHANIA TETRANDBRAE EXTRACT

Package Label - Principal Display Panel

彩盒尺寸29.5*29.5*126.6
370g银卡，逆向

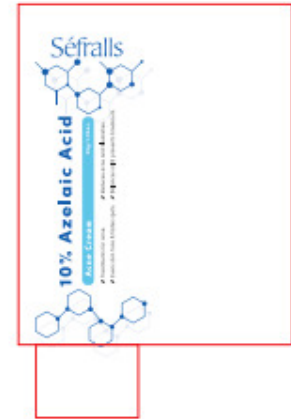


pantone 7455C

pantone 2985C



软管尺寸77*96



10% AZELAIC ACID ACNE CREAM

10% azelaic acid acne cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84148-009
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASIATICOSIDE (UNII: PK039VY215) (ASIATICOSIDE - UNII:PK039VY215)	ASIATICOSIDE	0.015 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
AZELAIC ACID (UNII: F2VW3D43YT) (AZELAIC ACID - UNII:F2VW3D43YT)	AZELAIC ACID	10 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 ETHANE SULFONIC ACID - UNII:RWW266YE9I)	HYDROXYETHYLPIPERAZINE ETHANE SULFONIC ACID	0.5 g in 100 g
TARAXACUM OFFICINALE LEAF (UNII: 0022LFJ74Y) (TARAXACUM OFFICINALE LEAF - UNII:0022LFJ74Y)	TARAXACUM OFFICINALE LEAF	0.01 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84148-009-01	30 g in 1 BOTTLE; Type 0: Not a Combination Product	09/29/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/29/2024	

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

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Ariel Biotech Co., Ltd.		402818771	manufacture(84148-009)

Revised: 9/2024

Guangzhou Ariel Biotech Co., Ltd.