

ATRIX ACNE TREATMENT- salicylic acid cream
PureTek Corporation

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.

Atrix™ Acne Treatment Cream

Drug Facts

Active ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Uses:

- for the treatment of acne
- dries and clears acne pimples, acne blemishes, whiteheads and blackheads
- helps prevent the development of new acne pimples, acne blemishes, whiteheads and blackheads

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- rinse right away with water if it gets in eyes.

Stop use and ask a doctor

- if skin irritation occurs or gets worse

Keep out of reach of children.

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

Directions

- Clean the skin thoroughly before applying this product
- cover the entire affected area with a thin layer one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Use under the direction of a medical practitioner.

Other information

- protect from freezing
- avoid excessive heat

Store at 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Avoid excessive heat. Do not use if package is damaged.

Keep this and all medication out of reach of children.

Inactive ingredients

Allyl Methacrylates Crosspolymer, Aqua (Purified Water), Butylene Glycol, Caprylyl Glycol, Carbomer, Cetearyl Olivatate, Cyclopentasiloxane, Decyl Glucoside, Dimethicone, Dipotassium Glycyrrhizinate, Disodium EDTA, Ethylhexylglycerin, Alpha-Glucan Oligosaccharide, Glucosamine HCl, Glycerin, Glyceryl Stearate SE, Hexylene Glycol, Laminaria Digitata (Algae) Extract, Oligopeptide- 10, Palmitic Acid, Phenoxyethanol, Polysilicone-11, Saccharomyces Cerevisiae Extract, Sodium Ascorbyl Phosphate, Sodium Hydroxide, Sorbitan Olivatate, Stearic Acid, DL- alpha- Tocopheryl Acetate, Urea

Call toll-free:

1-877-921-7873

Atrix Acne Cream

Packaged for :

PureTek Corporation

Panorama City, CA 91402

For questions or information
call toll-free: **877-921-7873**

NDC 59088-446-05

Atrix™

Medicated Formula

DERMACIN®

2% Salicylic Acid

Use under the direction of a medical practitioner

Acne Treatment Cream (2 fl oz) 59 mL Rev. 38264

See enclosed insert(s) for product information.

Store at 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Avoid excessive heat. Do not use if package is damaged.

Keep this and all medication out of reach of children.

Manufactured in the USA by:
PureTek Corporation
San Fernando, CA 91340
For questions or information
call toll-free: **877-921-7873**



List No. 44605JPA Rev. 38265



ATRIX ACNE TREATMENT

salicylic acid cream

Product Information

| | | | |
|---------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59088-446 |
|---------------------|----------------|---------------------------|---------------|

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 20 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| UREA (UNII: 8W8T17847W) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: B9J55EA6QX) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| .ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W) | |
| SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR) | |
| GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| OLIGOPEPTIDE-10 (UNII: Q46328TRNK) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| LAMINARIA DIGITATA (UNII: 15E7C67EE8) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| CETEARYL OLIVATE (UNII: 58B69Q84JO) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SORBITAN OLIVATE (UNII: MDL271E3GR) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59088-446-05 | 59 mL in 1 TUBE; Type 0: Not a Combination Product | 04/06/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part333D | 04/06/2021 | |

Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation