

**ATRIX SYSTEM 1- salicylic acid**  
**PureTek Corporation**

*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.*

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**AtrixSystem 1**

**ATRIX ACNE TREATMENT CREAM (2 fl oz ) 59 mL**  
**ATRIX ANTIBACTERIAL WASH (4 fl oz ) 118 mL**

**10/19- update marketing date**

**Atrix™ Acne Treatment Cream (2 fl oz ) 59 mL**

***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 Oliviate, 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 Oliviate, Stearic Acid, DL- alpha- Tocopheryl Acetate, Urea

Call toll-free:

**1-877-921-7873**

**Atrix™ Antibacterial Wash (4 fl oz ) 118 mL**

## **Active ingredient**

Salicylic Acid 2%

## **Purpose**

Acne treatment

## **Use**

- 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**

- Cleanse twice a day.
- Wet face. Apply to hands, add water and work into a lather.
- Massage face gently.
- Rinse thoroughly and pat dry 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 20° to 25°C (68° to 77°F)  
[see USP Controlled Room Temperature].**

## **Inactive ingredients**

Aqua (Purified Water), Cetyl Hydroxyethylcellulose, Citrus Paradisi (Grapefruit) Peel Oil, Cocamidopropyl Betaine, Disodium EDTA, Ethoxydiglycol, Glycerin, Lauryl Glucoside, Menthol, Menthyl Lactate, Pyrus Malus (Apple) Fruit Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sambucus Nigra (Elderberry) Fruit Extract, Sodium Lauryl Glucose Carboxylate.

## **Questions?**

Call toll-free:

**1-877-921-7873**

**Atrix™ System**

NDC 59088-713-00



# Atrix™ System 1

Helps treat and prevent the development  
of acne and blemishes

Use under the direction of a medical practitioner

**ATRIX ACNE TREATMENT CREAM**  
(2 fl oz) 59 mL

**ATRIX ANTIBACTERIAL WASH**  
(4 fl oz) 118 mL

See enclosed insert(s) for product information.

Store at 20° to 25°C (68° to 77°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.

Packaged for :  
**PureTek Corporation**  
Panorama City, CA 91402  
For questions or information  
call toll-free: 877-921-7873



List No. 71300IAY Rev. 38341



## ATRIX SYSTEM 1

salicylic acid kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59088-713
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-713-00	1 in 1 KIT; Type 0: Not a Combination Product	10/25/2021	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	59 mL
Part 2	1 BOTTLE	118 mL

## Part 1 of 2

### ATRIX ACNE TREATMENT

salicylic acid cream

## Product Information

Item Code (Source)	NDC:59088-446
Route of Administration	TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
WATER (UNII: 059QF0KO0R)	
GLUCOSAMINE HYDROCHLORIDE (UNII: 750W5330FY)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
OLIGOPEPTIDE-10 (UNII: Q46328TRNK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
SACCHAROMYCES CEREVISIAE (UNII: 978D8U419H)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
UREA (UNII: 8W8T17847W)	
.ALPHA.-GLUCAN OLIGOSACCHARIDE (UNII: S95658MI3W)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>PALMITIC ACID</b> (UNII: 2V16EO95H1)	
<b>LAMINARIA DIGITATA</b> (UNII: 15E7C67EE8)	
<b>ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: B9J55EA6QX)	

## 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		

## Marketing Information

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

## Part 2 of 2

### ATRIX ANTIBACTERIAL WASH

salicylic acid liquid

## Product Information

<b>Item Code (Source)</b>	NDC:59088-445
<b>Route of Administration</b>	TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>GRAPEFRUIT OIL</b> (UNII: YR377U58W9)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)	
<b>APPLE</b> (UNII: B423VGH5S9)	
<b>ROSEMARY</b> (UNII: IJ67X351P9)	
<b>.ALPHA.-IONENE</b> (UNII: B2ZN1K7W3Q)	

<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>EUROPEAN ELDERBERRY</b> (UNII: BQY1UBX046)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CETYL HYDROXYETHYLCELLULOSE (350000 MW)</b> (UNII: T7SWE4S2TT)	
<b>LAURYL GLUCOSIDE</b> (UNII: 76LN7P7UCU)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>SODIUM LAURYL GLYCOL CARBOXYLATE</b> (UNII: 8L0472VMYL)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-445-08	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	01/05/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/25/2021	

**Labeler** - PureTek Corporation (785961046)