AQUA PLUS ACNE TREATMENT SYSTEM- salicylic acid
Totally Clear Products, Inc

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.

Aqua Plus Acne Treatment System

daily CLEANSER

Drug Facts

Active Ingredients

Salicylic Acid 2.0%

Purpose

Acne Treatment

Uses

For The Treatment of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- 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.
- Limit use to face and neck.

Keep Out Of Reach Of Children

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

Directions

Wet your skin and massage the Aqua+ Daily Cleanser over your entire face, avoiding your eyes. Use the Aqua+ Daily Cleanser only once a day until your skin acclimates, after which you can move to twice-per-day applications. Rinse with water and gently pat your skin with a clean towel.

Water, Sodium Laureth Sulfate, Cetyl Alcohol, Glycerin, Aloe Barbadensis Leaf Extract, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Glyceryl Stearate, Green Tea (Camellia Sinensis) Leaf Extract, Sodium Ascorbic Phosphate, dl-Panthenol, Tocopheryl Acetate, Retinyl Palmitate, Xanthum Gum, Steareth-21, Squalane, Dimethicone, Polysorbate-60, Cprylyl Glycol, Steareth-2, Versene Na, Phosphoric Acid, Propylene Glycol, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

refreshing TONER

Drug Facts

Active Ingredients

Salicylic Acid 1.0%

Purpose

Acne Treatment

Uses

For The Treatment Of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- 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.
- Limit use to face and neck.

Keep Out Of Reach Of Children

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

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Isoceteh-20, Salix Alba (Willow) Bark Extract, Methyl Gluceth-20, Caprylyl Glycol, Tetrasodium EDTA, Sodium Hydroxide, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methlisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

spotter GEL

Drug Facts

Active Ingredients

Salicylic Acid 1.5%

Purpose

Acne Treatment

Uses

For The Treatment Of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- 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.
- Limits use to face and neck.

Keep Out Of Reach Of Children

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

Directions

Clean the skin thoroughly before applying the Aqua+ Spotter Gel. 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.

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Butylene Glycol, Polyquaternium-10, Spirea ulmaria (Meadowsweet) Flower Extract, Triticum Vuldare (Wheat) Germ Extract, Tetrasodium ETDA, Caprylyl Glycol, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

System Labeling

Aqua Plus Daily Cleanser

Aqua Plus Refreshing Toner Label

AQUAPLUS SERIES

ACNE TREATMENT

refreshing
TONER

Salicylic Acid 1%

50ml

NDC 71471-416-27

Drug Facts

Active Ingredients	Purpose	Uses
Salicylic Acid 1.0%	Acne Treatment	For The Treatment Of Acne

Warnings - For External Use Only

When Using This Product:

- Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water.
- 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.
- Limit use to face and neck.

Keep Out Of Reach Of Children

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

Directions

After cleansing your face with the Aqua+ Daily Cleanser, apply the Aqua+ Refreshing Toner with a cotton ball or soft tissue. Start to rub cotton ball over entire face. Pay extra attention to acne prone areas such as nose and cheeks. Let dry. Do not rinse. Will reduce oil and impurities and restores natural balance to skin.

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Isoceteth-20, Salix Alba (Willow) Bark Extract, Methyl Gluceth-20, Caprylyl Glycol, Tetrasodium EDTA, Sodium Hydroxide, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information

Store in a cool, dry place. Do not freeze.

Questions? 1-888-407-8330 www.aqplus.com

Totally Clear Products, Inc.
Lake Worth, FL 33463

Made in the USA

Aqua Plus Spotter Gel Label

AQUAPLUS SERIES

ACNE TREATMENT

spotter
GEL

Salicylic Acid 1.5%

30ml

NDC 71471-312-27

Drug Facts

Active Ingredients	Purpose	Uses
Salicylic Acid 1.5%	Acne Treatment	For The Treatment Of Acne

Warnings - For External Use Only • **WHEN USING THIS PRODUCT:** • Avoid contact with eyes and mouth. If contact occurs, rinse thoroughly with water. • 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. • Limit use to face and neck. • **KEEP OUT OF REACH OF CHILDREN:** • If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions: • Clean the skin thoroughly before applying the Aqua+ Spotter Gel. • 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.

Water, Propylene Glycol, SD Alcohol 40B, Cocamidopropyl Dimethylamine, Butylene Glycol, Polyquaternium-10, Spiraea Ulmaria (Meadowsweet) Flower Extract, Triticum Vuldare (Wheat) Germ Extract, Tetrasodium ETDA, Caprylyl Glycol, Phosphoric Acid, Hydrobromic Acid, Citric Acid, Glutaric Acid, Methylisothiazolinone

Other Information
Store in a cool, dry place. Do not freeze.

Questions?
1-888-407-8330 www.aqplus.com

Totally Clear Products, Inc. • Lake Worth, FL 33463

Made in the USA

AQUA PLUS ACNE TREATMENT SYSTEM

salicylic acid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71471-269

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71471-269-27	1 in 1 BOX; Type 1: Convenience Kit of Co-Package	09/01/2017	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	50 mL
Part 2	1 BOTTLE	30 mL
Part 3	1 BOTTLE	50 mL

Part 1 of 3

AQUA PLUS DAILY CLEANSER

salicylic acid solution

Product Information	
Item Code (Source)	NDC:71471-561
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)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
PANTHENOL (UNII: WV9CM0O67Z)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARETH-21 (UNII: 53J3F32P58)	
SQUALANE (UNII: GW89575KF9)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARETH-2 (UNII: V56DFE46J5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROBROMIC ACID (UNII: 3IY7CNP8XJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLUTARIC ACID (UNII: H849F7N00B)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71471-561-27	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/01/2017	

Part 2 of 3

AQUA PLUS SPOTTER GEL

salicylic acid gel

Product Information

Item Code (Source)	NDC:71471-312
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

WHEAT GERM (UNII: YR3G369F5A)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROBROMIC ACID (UNII: 3IY7CNP8XJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLUTARIC ACID (UNII: H849F7N00B)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71471-312-27	30 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/01/2017	

Part 3 of 3

AQUA PLUS REFRESHING TONER

salicylic acid solution

Product Information

Item Code (Source)	NDC:71471-416
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COCAMIDOPROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
ISOCETETH-20 (UNII: O020065R7Z)	
WILLOW BARK (UNII: S883J9JDYX)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE SODIUM (UNII: MP1J8420LU)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
HYDROBROMIC ACID (UNII: 3IY7CNP8XJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLUTARIC ACID (UNII: H849F7N00B)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71471-416-27	50 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/01/2017	

Labeler - Totally Clear Products, Inc (080687729)

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