

CLARIFAST ONE STEP ACNE TREATMENT- salicylic acid cream
VIREO SYSTEMS, INC.

CLARIFAST One Step Acne Treatment

Drug Facts

Active ingredient

Salicylic Acid 0.5 %

Purpose

Acne Treatment

Uses:

- For the treatment of acne.
- Helps clear acne blemishes, pimples, and blackheads.
- Penetrates pores to reduce the number of acne blemishes, pimples and blackheads.
- Helps prevent new acne blemishes, pimples, and blackheads from forming.
- Helps prevent the development of new acne blemishes, pimples 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.

Keep out of reach of children.

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

If pregnant or breast-feeding,

ask a health professional before use.

Directions:

- Apply to affected area and rub in lightly, one to two times daily (before bedtime or anytime during the day as desired). Allow 30 minutes to dry
- If drying of the skin occurs, reduce application to once a day, every other day, or as directed by a doctor.

Other information:

- Protect the product in this container from excessive heat and direct sun. Store at a controlled room temperature 20-25C (68-77F).

Inactive ingredients:

Alpha-GEE®, Aloe Barbadensis Leaf Extract, Amezol®, Bellis Perennis Flower Extract, Cetyl Alcohol, Coconut Oil, Colloidal Oatmeal, Denatured Alcohol, Glyceryl Monostearate, Hamamelis Virginiana Extract 3X, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Polyethylene Glycol 400, Polyethylene Glycol 3350, Potassium Phosphate Dibasic, Propylene Glycol, Sulfur 1X, Zinc Oxide.

Package Labeling:

<p>Salicylic Acid is a natural extract found in willow bark and other natural sources.</p> <p>PROPRIETARY INGREDIENTS</p> <p>Alpha-GEE® and Amezol® are unique peptide compounds conjugated from various essential and conditionally essential amino acids found in natural sources.</p>   <p>Manufactured in the USA for Vireo Systems, Inc. 305 Williams Ave. Madison, TN 37115 1-855-442-6466 vireosystems.com</p>	<p>FORMULATED WITH AMEZOL® AND ALPHA-GEE®</p>  <p>81.33 mL / 2.75 fl oz</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active Ingredient</th> <th>Purpose</th> </tr> <tr> <td>Salicylic Acid 0.5 %</td> <td>Acne Treatment</td> </tr> </table> <p>Uses:</p> <ul style="list-style-type: none"> • For the treatment of acne. • Helps clear acne blemishes, pimples, and blackheads. • Penetrates pores to reduce the number of acne blemishes, pimples and blackheads. • Helps prevent new acne blemishes, pimples, and blackheads from forming. • Helps prevent the development of new acne blemishes, pimples and blackheads. <p>Warnings: for external use only.</p> <p>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.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active Ingredient	Purpose	Salicylic Acid 0.5 %	Acne Treatment	<p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Directions:</p> <ul style="list-style-type: none"> • Apply to affected area and rub in lightly, one to two times daily (before bedtime or anytime during the day as desired). Allow 30 minutes to dry - If drying of the skin occurs, reduce application to once a day, every other day, or as directed by a doctor. <p>Other information:</p> <ul style="list-style-type: none"> • Protect the product in this container from excessive heat and direct sun. Store at a controlled room temperature 20-25C (68-77F). <p>Inactive ingredients: Alpha-GEE®, Aloe Barbadensis Leaf Extract, Amezol®, Bellis Perennis Flower Extract, Cetyl Alcohol, Coconut Oil, Colloidal Oatmeal, Denatured Alcohol, Glyceryl Monostearate, Hamamelis Virginiana Extract 3X, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Polyethylene Glycol 400, Polyethylene Glycol 3350, Potassium Phosphate Dibasic, Propylene Glycol, Sulfur 1X, Zinc Oxide.</p>
Active Ingredient	Purpose						
Salicylic Acid 0.5 %	Acne Treatment						

CLARIFAST ONE STEP ACNE TREATMENT

salicylic acid cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82908-358
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BELLIS PERENNIS FLOWER (UNII: 26I94X9A1K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OATMEAL (UNII: 8PI54V663Y)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

TEA TREE OIL (UNII: VIF565UC2G)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82908-358-00	81.33 mL in 1 JAR; Type 0: Not a Combination Product	08/08/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	08/08/2022	

Labeler - VIREO SYSTEMS, INC. (832940295)

Revised: 11/2023

VIREO SYSTEMS, INC.