

## **ULTRA CLEAR FOAMING CLEANSER ACNE- salicylic acid lotion**

**Ultraceuticals US, LLC**

*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.*

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### **Ultra Clear Foaming Cleanser**

#### **Acne Face Cleanser**

#### **Active Ingredients Purpose**

Salicylic Acid 0.5% w/w Acne Treatment

#### **Uses**

- For treatment of ACne
- Clear acne blemishes

For external use only

#### **Stop use and ask a doctor:**

- if skin irritation becomes severe

#### **Warnings**

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 m

#### **Directions**

- Clean the skin thoroughly before applying this product.
- Cover the entire affected area with a thin layer and rinse thoroughly 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 dryness or peeling occurs, reduce application to once a day or every other day.

#### **Inactive Ingredient**

Water/Eau, Polysorbate 20, Methylpropanediol, Decyl Glucoside, PEG-120 Methyl Glucose Dioleate, Lactic Acid, Hamamelis Virginiana Water, Cocamidopropyl Betain, Sodium Hydroxide, Mandelic Acid, Caprylyl Glycol, Sodium Lauroyl Lactylate, Allantoin, Sodium Chloride, Sodium PCA, Disodium EDTA, Phenylpropanol, Niacinamide, Disodium Lauriminodipropionate Tocopheryl Phosphates, Eucalyptus Globulus Leaf Oil, Fusanus Spicatus Wood Oil, Eugenia Caryophyllus (Clove) Bud Oil, Sodium Benzoate, Benzoic acid, Phenoxyethanol, Dehydroacetic Acid.

Ultraceuticals

Ultra Clear Foaming Cleanser

with Mandelic & Salicylic Acid

Acne Face Cleanser

™





Real Skincare. Real Results.

ULTRACEUTICALS

Ultra Clear  
Foaming Cleanser  
with Mandelic &  
Salicylic Acids  
Acne Face Cleanser

Ultraceuticals products are developed to provide optimal results when professionally recommended.

Non-Bleaching • Benzoyl Peroxide Free • Formulated in Australia

Contains natural aroma extracted from plants.

This foaming cleanser helps improve surface shine, remove impurities and unclog pores. This powerful formula combines Niacinamide with exfoliators (Salicylic Acid & Mandelic Acid) to help remove excess sebum and deeply cleanse pores. This cleanser contains Allantoin to help condition skin leaving it feeling balanced and healthy.



CLT-224-150

150 mL / 5.07 fl. OZ.

Made in Australia

Distributed by:  
Ultraceuticals Pty Ltd  
Suite 2, Level 4, 436-484 Victoria Road  
Gladesville NSW 2111 AUSTRALIA

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DRUG FACTS	
<b>Active ingredients</b>	<b>Purpose</b>
Salicylic Acid 0.5% w/w.....	Acne Treatment
<b>Uses</b>	
<ul style="list-style-type: none"> <li>For treatment of acne.</li> <li>Clears acne blemishes.</li> </ul>	
<b>WARNINGS</b>	
For external use only.	
<b>When using this product:</b>	
<ul style="list-style-type: none"> <li>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.</li> </ul>	
<b>When using this product:</b>	
<ul style="list-style-type: none"> <li>Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water to remove.</li> <li>If irritation occurs, only use one topical medication at a time.</li> </ul>	
<b>Stop use and seek a doctor:</b>	
<ul style="list-style-type: none"> <li>If skin irritation becomes severe.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>Clean the skin thoroughly before applying this product.</li> <li>Cover the entire affected area with a thin layer and rinse thoroughly one to three times daily.</li> <li>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.</li> <li>If dryness or peeling occurs, reduce application to once a day or every other day.</li> </ul>	
<b>INACTIVE INGREDIENTS:</b>	
Water/Eau, Polysorbate 20, Methylpropanediol, Decyl Glucoside, PEG-120 Methyl Glucose Dioleate, Lactic Acid, Hamamelis Virginiana Water, Cocamidopropyl Betaine, Sodium Hydroxide, Mandelic Acid, Caprylyl Glycol, Sodium Lauryl Lactylate, Allantoin, Sodium Chloride, Sodium PCA, Disodium EDTA, Phenylpropanol, Niacinamide, Disodium Lauriminodipropionate Tocopheryl Phosphates, Eucalyptus Globulus Leaf Oil, Ficusus Spicatus Wood Oil, Eugenia Caryophyllus (Clove) Bud Oil, Sodium Benzoate, Benzoic Acid, Phenoxyethanol, Dehydroacetic Acid.	
<b>Other information</b>	
Store below 25°C / 77°F	
<b>Questions?</b>	
Call 833 703 9067	



CLT-224-150C1

**ULTRA CLEAR FOAMING CLEANSER ACNE**  
salicylic acid lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73122-125
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.5 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
LACTIC ACID (UNII: 33X04XA5AT)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
MANDELIC ACID (UNII: NH496X0UJX)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
SANTALUM SPICATUM OIL (UNII: H9LVS6REV4)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
NIACINAMIDE (UNII: 25X51I8RD4)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
CLOVE OIL (UNII: 578389D6D0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-125-01	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2019	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part333D	09/26/2019	
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**Labeler** - Ultraceuticals US, LLC (117022448)

**Establishment**

Name	Address	ID/FEI	Business Operations
Baxter Laboratories Pty Ltd		740537709	manufacture(73122-125)

Revised: 9/2019

Ultraceuticals US, LLC