

ULTRA CLEAR FOAMING CLEANSER- salicylic acid lotion
ULTRACEUTICALS PTY LIMITED

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.

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

When using this product:

Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water to remove.

If irritation occurs, only use one topical medication

Stop use and ask a doctor:

if skin irritation becomes severe

Warnings

For External use only.

- 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.

Directions

Clean the skin thoroughly before applying this product.

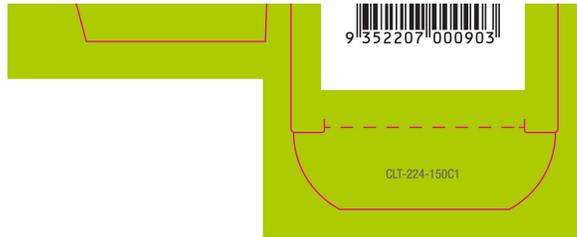
Cover the entire affected area with a thin layer and rinse thoroughly one to three times daily.

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 Ingredients

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 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.



ULTRA CLEAR FOAMING CLEANSER

salicylic acid lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10028-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
PHENYLPROPANOL (UNII: 0F897O3O4M)	
NIACINAMIDE (UNII: 25X5118RD4)	
SANTALUM SPICATUM OIL (UNII: H9LVS6REV4)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
LACTIC ACID (UNII: 33X04XA5AT)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
CLOVE OIL (UNII: 578389D6D0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MANDELIC ACID (UNII: NH496X0UJX)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10028-050-01	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2019	
2	NDC:10028-050-02	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	12/11/2019	

Labeler - ULTRACEUTICALS PTY LIMITED (744068995)

Revised: 9/2023

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