

**ULTRA CLEAR TREATMENT- 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 Treatment Lotion**  
**with salicylic and mandelic acid**

**Active Ingredients Purpose**

Salicylic Acid 2% w/w Acne Treatment

**Uses**

- For treatment of acne
- Helps clear acne blemishes and acne pimples

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

**Stop use and ask a doctor:**

- If skin irritation becomes severe

**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.

**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 dryness or peeling occurs, reduce application to once a day or every other day.

**Inactive ingredients:**

Water/Eau, PPG-15 Stearyl Ether, Arginine, Glycerin, Mandelic Acid, Niacinamide, Tribehenin PEG-20 Esters, Ethoxydiglycol, Methylpropanediol, Cetearyl Alcohol, Disodium Laurimodipropionate Tocopheryl Phosphates, Dimethicone, Bentonite, Caprylyl Glycol, Allantoin, Bisabolol, Hydrated Silica, Sodium PCA, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polyacrylate Crosspolymer-6 Xanthan Gum, Disodium EDTA, Phenylpropanol, Eucalyptus Globulus Leaf Oil, Fusanus Spicata Wood Oil, Phenoxyethanol, Eugenia Caryophyllus (Clove) Bud Oil, Aloe Barbadosensis Leaf Juice Powder, Maltodextrin, T-Butyl Alcohol, Benzoic Acid, Dehydroacetic Acid.

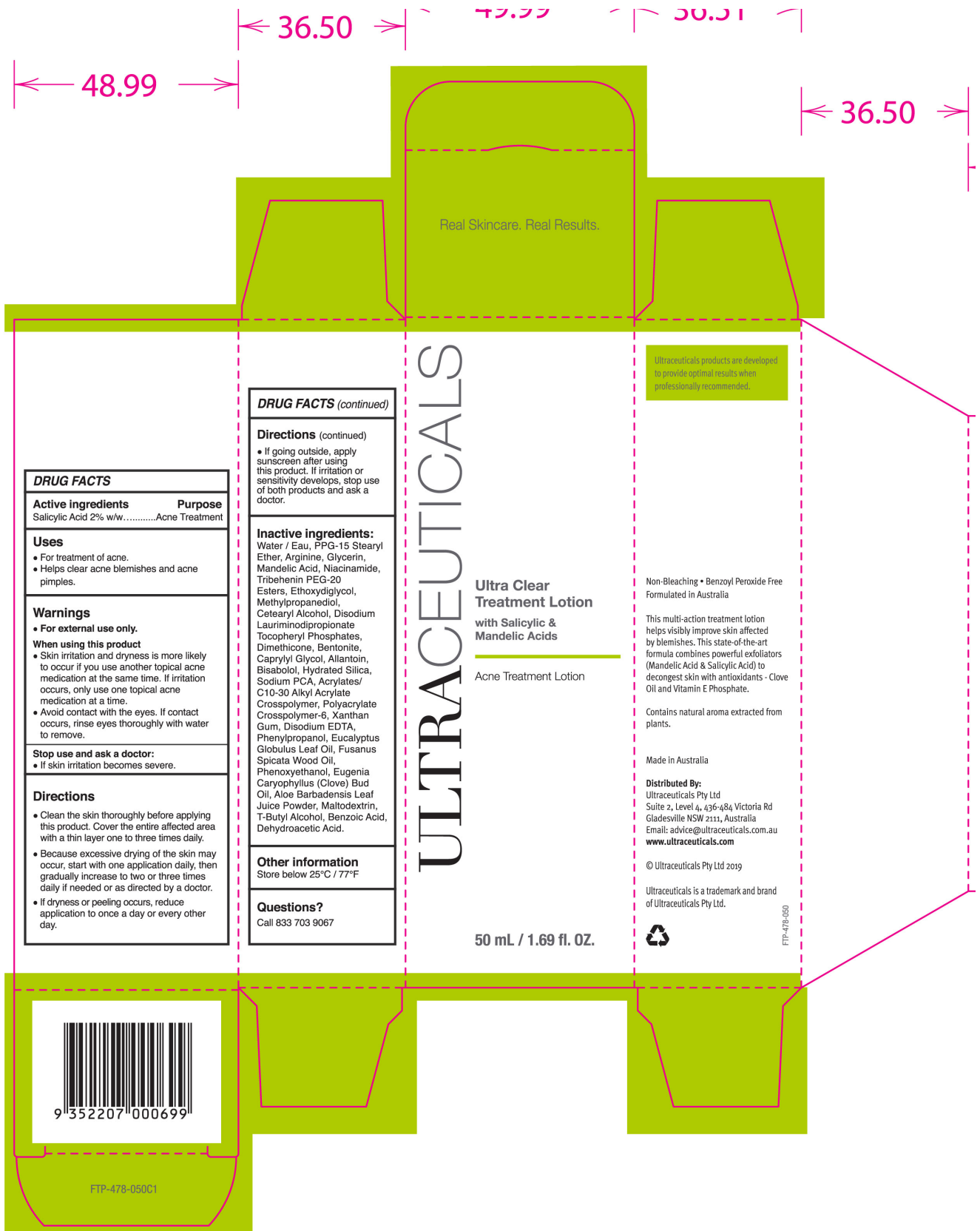
Ultraceuticals

Ultra Clear Treatment Lotion

with Salicylic & Mandelic Acid

Acne Treatment Lotion

50mL / 1.69 fl OZ



## ULTRA CLEAR TREATMENT

salicylic acid lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73122-126
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
MANDELIC ACID (UNII: NH496X0UJX)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
ALLANTOIN (UNII: 344S277G0Z)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CLOVE OIL (UNII: 578389D6D0)	
SANTALUM SPICATUM OIL (UNII: H9LVS6REV4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DISODIUM LAURIMINODIPROPIONATE TOCOPHERYL PHOSPHATES (UNII: 0K5Y9U1P6M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BENTONITE (UNII: A3N5ZCN45C)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LEVOMENOL (UNII: 24WE03BX2T)	
WATER (UNII: 059QF0K00R)	
PPG-15 STEARYL ETHER (UNII: 1II18XLS1L)	
ARGININE (UNII: 94ZLA3W45F)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACINAMIDE (UNII: 25X51I8RD4)	
TRIBEHENIN PEG-20 ESTERS (UNII: 84K9EH29Y9)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:73122-126-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/26/2019	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part333D		09/26/2019	

**Labeler** - Ultraceuticals US LLC (117022448)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Baxter Laboratories Pty. Ltd.		740537709	manufacture(73122-126)

Revised: 9/2019

Ultraceuticals US LLC