CLEARASIL ULTRA OVERNIGHT FACE- salicylic acid lotion RB Health (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.

Clearasil ® ULTRA ®

Drug Facts

Active Ingredient

Salicyclic acid 2%

Purpose

Acne Medication

Use

for the treatment of acne

Warnings

For external use only

When using this product

- Avoid contact with the eyes. If product gets into the eyes, rinse thoroughly with water
- With other topical acne medications, at the same time or immediately following use of this product, increased dryness or irritation of the skin may occur. If this occurs, only one acne medication should be used unless directed by your doctor
- Limit use to the face and neck

Stop use and ask a doctor if skin or eye irritation develops.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- Cleanse the skin thoroughly before applying medication
- 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 2 or 3 applications daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every

Other information

- Store in a cool, dry place
- Keep outer packaging for precautions and directions

Inactive ingredients

Water, Butylene Glycol, Octyldodecanol, Steareth-2, Cetyl Alcohol, Steareth-21, Dimethicone, Polyacrylamide Glycerin, C13-14 Isoparaffin, Phenoxyethanol, Sodium Hydroxide, Xanthan Gum, Magnesium Aluminum Silicate, Laureth-7, Fragrance, Lavandula Stoechas Extract, Helichrysum Italicum Extract, Cistus Monspeliensis Extract, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben, Propylparaben, Titanium Dioxide

Questions?

Call 1-866-25-CLEAR (1-866-252-5327).

You may also report side effects to this phone number.

Distributed by: Reckitt Benckiser LLC Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 38.4 mL Tube Carton

Clearasil®

ULTRA[®]

Overnight Face Lotion

Salicylic Acid 2% Acne Medication

Helps visibly reduce pimple size and redness overnight

1.3 FL. OZ. (38.4 mL)



CLEARASIL ULTRA OVERNIGHT FACE

salicylic acid lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63824-339

SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ) SALICYLIC ACID 2 g in 100 Inactive Ingredients Ingredient Name Strengt WATER (UNII: 059QF0K00R) BUTYLENE GLYCOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 340195405) CETYL ALCOHOL (UNII: 936]516[CN) STEARETH-2 (UNII: 593732P58) DIMETHICONE (UNII: 93732P58) DIMETHICONE (UNII: 92RU3N310) C13-14 ISOPARAFFIN (UNII: E4F12R0E70) PHENOXYETHANOL (UNII: 507040232) XANTHAN GUM (UNII: T12P4NEE) AGGING HUMI: T12P4NEE) AGGING HUMI: T141CUM FLOWER OIL (UNII: 70759G2U6A) HELICHYSUM ITALICUM FLO				
Ingredient Name Basis of Strengt Strengt SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ) SALICYLIC ACID 2 g in 100 Inactive Ingredients Ingredient Name Strengt WATER (UNII: 059QF0K00R) Ingredient Name Strengt WATER (UNII: 059QF0K00R) Ingredient Name Strengt WATER (UNII: 059QF0K00R) Ingredient Name Strengt STEARETH-2 (UNII: 3305380 Ingredient Name Ingredient Name STEARETH-2 (UNII: 9305156)(N) Ingredient Name Ingredient Name STEARETH-2 (UNII: 53)352P58) Ingredient Name Ingredient Name DIMETHICONE (UNII: 920303Y10) Ingredient Name Ingredient Name C13-14 ISOPARAFFIN (UNII: E4F12R0E70) Ingredient Name Ingredient Name PHENOXYETHANOL (UNII: E4F12R0E70) Ingredient Name Ingredient Name Machesium ALUMINUM SILCATE (UNII: 643P64V0NC) Ingredient Name Ingredient Name Machesium ALUMINUM SILCATE (UNII: 70759G2U6A) Ingredient Name Ingredient Name Helichrysum Italicum Flower OIL (UNII: 70759G2U6A) Ingredient Name Ingredient Name BUTYLPARABEN (UNII: 328256G8201) Ingredient Name Ingredient Name <td< th=""><th>Active Ingredi</th><th>ent/Active Moiety</th><th></th><th></th></td<>	Active Ingredi	ent/Active Moiety		
SALICYLIC ACID (UNII: 0414PZ4LPZ) SALICYLIC ACID 2 g in 100 Inactive Ingredients Strengt Ingredient Name Strengt Marce (UNII: 059QF0K00R) Strengt BUTYLENE GLYCOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 34015616(N) STEARETH-2 (UNII: 50365616(N) STEARETH-2 (UNII: 5365676(N) STEARETH-2 (UNII: 53657676) STEARETH-2 (UNII: 53736758) DIMETHICONE (UNII: 32057670) PHENOXYETHANOL (UNII: E4F12R0E70) PHENOXYETHANOL (UNII: E4F12R0E70) PHENOXYETHANOL (UNII: TV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: Z955668201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HETHYLPARABEN (UNII: 320871H9T) BUTYLPARABEN (UNII: 32082C10H) ETHYLPARABEN (UNII: 261X25C10H) ITANIUM DIOXIDE (UNII: 15FIX9V2JP)		•	Basis of Stre	ngth Strength
Inactive Ingredients Ingredient Name Strengt WATER (UNI: 059QF0KO0R) BUTYLENE GLYCOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 3XUS85K0RA) OCTYLDODECANOL (UNII: 4611N0614Y) STEARETH-2 (UNI: 550FE46J5) CETYL ALCOHOL (UNII: 936JST6JCN) STEARETH-2 (UNII: 553J3F32P58) DIMETHICONE (UNII: 593J3F32P58) SODIUM HYDROXIDE (UNII: 512R0E70) HENOXYETHANOL (UNII: HE492Z 3T) SODIUM HYDROXIDE (UNII: 50504QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: 2955G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097Z V7726K) METHYLPARABEN (UNII: 3QP1U3FV8) ETHYLPARABEN (UNII: 4285C7H9T) BUTYLPARABEN (UNII: 4285C7H9T) BUTYLPARABEN (UNII: 42852C10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # tem Code Package Description Marketing Start Marketing EI	SALICYLIC ACID (L	-		2 g in 100 mL
Ingredient NameStrengtWATER (UNII: 059QF0K00R)Imgredient NameImgredient NameBUTYLENE GLYCOL (UNII: 3XU\$85K0RA)OCTYLDODECANOL (UNII: 3XU\$85K0RA)Imgredient NameOCTYLDODECANOL (UNII: 451N10614Y)STEARETH-2 (UNII: v56DFE46J5)Imgredient NameCETYL ALCOHOL (UNII: 936J5T6JCN)STEARETH-2 (UNII: v56DFE46J5)Imgredient NameSTEARETH-21 (UNII: 936J5T6JCN)STEARETH-21 (UNII: 53J3F32P58)Imgredient NameDIMETHICONE (UNII: 92RU3N3Y10)Imgredient NameImgredient NameC13-14 ISOPARAFFIN (UNII: E4F12ROE70)PHENOXYETHANOL (UNII: HE492ZZ3T)Imgredient NameSODIUM HYDROXIDE (UNII: 55X04QC32I)XANTHAN GUM (UNII: TTV12P4NEE)Imgredient NameMAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)Imgredient NameImgredient NameLAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A)Imgredient NameImgredient NameHELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K)Imgredient NameImgredient NameBUTYLPARABEN (UNII: 328C7H19T)Imgredient NameImgredient NameBUTYLPARABEN (UNII: 281X25C10H)Imgredient NameImgredient NameTITANIUM DIOXIDE (UNII: 151K9V2)P)Imgredient NameImgredient NamePackaging# Item CodePackage DescriptionMarketing StartMarketing Ei				
WATER (UNII: 059QF0K00R) Image: Content of the second	Inactive Ingre	dients		
BUTYLENE GLYCOL (UNII: 3XUS85KORA) OCTYLDODECANOL (UNII: 461N10614Y) STEARETH-2 (UNII: 506FE46J5) CETYL ALCOHOL (UNII: 936JST6JCN) STEARETH-21 (UNII: 53J3732P58) DIMETHICONE (UNII: 92RU3N3Y1O) C13-14 ISOPARAFFIN (UNII: E4F12ROE70) PHENOXYETHANOL (UNII: HIE492Z 3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: 295S6G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 32PI13FV8) ETHYLPARABEN (UNII: 32PI13FV8) ETHYLPARABEN (UNII: 32PI13FV8) ISOBUTYLPARABEN (UNII: 32PI125EXE39) ISOBUTYLPARABEN (UNII: 32PI255K3G) PROPYLPARABEN (UNII: 28IX25C10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) # them Code Packaging # them Code Package Package Description Marketing Start Marketing Et		Ingredient Name		Strength
OCTYLDODECANOL (UNII: 461N10614Y) Image: Control of C	WATER (UNII: 059Q	F0KO0R)		
STEARETH-2 (UNII: V56DFE46J5) CETYL ALCOHOL (UNII: 936JST6JCN) STEARETH-21 (UNII: 53J3F32P58) DIMETHICONE (UNII: 92RU3N3Y1O) C13-14 ISOPARAFFIN (UNII: E4F12ROE70) PHENOXYETHANOL (UNII: HIE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: 29556G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 3QP1U3FV8) ETHYLPARABEN (UNII: 3QP1U3FV8) ETHYLPARABEN (UNII: 28IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # them Code Package Description Marketing Start Marketing En	BUTYLENE GLYCO	L (UNII: 3XUS85K0RA)		
CETYL ALCOHOL (UNII: 936)5T6)CN) STEARETH-21 (UNII: 53)3F32P58) DIMETHICONE (UNII: 92RU3N3Y1O) C13-14 ISOPARAFFIN (UNII: E4F12ROE7O) PHENOXYETHANOL (UNII: HE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: Z9556G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 3QP11J3FV8) ETHYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 28IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # them Code Package Description Marketing Start Marketing Enter Start Start Marketing Enter Start Start Start Start Start Start Start Sta	OCTYLDODECANO	L (UNII: 461N1O614Y)		
STEARETH-21 (UNII: 53)3F32P58) DIMETHICONE (UNII: 92RU3N3Y10) C13-14 ISOPARAFFIN (UNII: E4F12ROE70) PHENOXYETHANOL (UNII: HE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: 2955668201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 328C7H19T) BUTYLPARABEN (UNII: 428C7H19T) BUTYLPARABEN (UNII: 1255EXE39) ISOBUTYLPARABEN (UNII: 16X2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) PACKaging # them Code Package Description Marketing Start Marketing Edited (Marketing Edited (Market	STEARETH-2 (UNII:	V56DFE46J5)		
DIMETHICONE (UNII: 92RU3N3Y10) C13-14 ISOPARAFFIN (UNII: E4F12ROE70) PHENOXYETHANOL (UNII: HIE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: Z95S6G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: A2I8C7H19T) BUTYLPARABEN (UNII: 3QP11U3FV8) ETHYLPARABEN (UNII: 3QP11U3FV8) ETHYLPARABEN (UNII: 1255X58G) PROPYLPARABEN (UNII: 28IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) # them Code Package Description Marketing Start Marketing Ether Start Marketin	CETYL ALCOHOL (UNII: 936JST6JCN)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70) PHENOXYETHANOL (UNII: HIE492ZZ3T) SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: Z9556G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 3QP11U3FV8) ETHYLPARABEN (UNII: 3QP11U3FV8) ETHYLPARABEN (UNII: 3QP125X58G) PROPYLPARABEN (UNII: 28X2SC10H) TITANIUM DIOXIDE (UNII: 15F1X9V2JP) Packaging # them Code Package Description Marketing Start Marketing Eter	STEARETH-21 (UN	II: 53J3F32P58)		
PHENOXYETHANOL (UNII: HIE492ZZ3T) Image: Control of the control o	DIMETHICONE (UN	III: 92RU3N3Y1O)		
SODIUM HYDROXIDE (UNII: 55X04QC32I) XANTHAN GUM (UNII: TTV12P4NEE) MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) LAURETH-7 (UNII: Z95S6G8201) LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: 32I8C7HI9T) BUTYLPARABEN (UNII: 32PI1U3FV8) ETHYLPARABEN (UNII: 32PI1U3FV8) ETHYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 28IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) # them Code Package Description Marketing Start Marketing Et	C13-14 ISOPARAF	FIN (UNII: E4F12ROE70)		
XANTHAN GUM (UNII: TTV12P4NEE) Image: Signal Si	PHENOXYETHANO	L (UNII: HIE492ZZ3T)		
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) Image: Constant of the state	SODIUM HYDROXI	DE (UNII: 55X04QC32I)		
LAURETH-7 (UNII: Z95S6G8201) Image: Content of Conten	XANTHAN GUM (UN	NII: TTV12P4NEE)		
LAVANDULA STOECHAS FLOWERING TOP (UNII: 70759G2U6A) HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) METHYLPARABEN (UNII: A218C7H19T) BUTYLPARABEN (UNII: 3QP11U3FV8) ETHYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 0QQJ25X58G) PROPYLPARABEN (UNII: 281X2SC10H) TITANIUM DIOXIDE (UNII: 15F1X9V2JP) Fackaging # them Code Package Description Marketing Start Marketing En	MAGNESIUM ALUM	IINUM SILICATE (UNII: 6M3P64V0NC)		
HELICHRYSUM ITALICUM FLOWER OIL (UNII: 097ZV7726K) Image: Constraint of the state of the	LAURETH-7 (UNII: 2	Z95S6G8201)		
METHYLPARABEN (UNII: A2I8C7HI9T) Image: Constraint of the state	LAVANDULA STOE	CHAS FLOWERING TOP (UNII: 70759G2U6A)		
BUTYLPARABEN (UNII: 3QPI1U3FV8) Image: Second state stat	HELICHRYSUM ITA	LICUM FLOWER OIL (UNII: 097ZV7726K)		
ETHYLPARABEN (UNII: 14255EXE39) ISOBUTYLPARABEN (UNII: 0QQJ25X58G) PROPYLPARABEN (UNII: Z8IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # Item Code Package Description Marketing Start Marketing En	METHYLPARABEN	(UNII: A2I8C7HI9T)		
ISOBUTYLPARABEN (UNII: 0QQJ25X58G) PROPYLPARABEN (UNII: Z8IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # Item Code Package Description Marketing Start Marketing En	BUTYLPARABEN (L	JNII: 3QPI1U3FV8)		
PROPYLPARABEN (UNII: Z8IX2SC10H) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # Item Code Package Description Marketing Start Marketing En	ETHYLPARABEN (L	JNII: 14255EXE39)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) Packaging # Item Code Package Description Marketing Start Marketing End	ISOBUTYLPARABE	N (UNII: 0QQJ25X58G)		
Packaging # Item Code Package Description Marketing Start Marketing El	PROPYLPARABEN	(UNII: Z8IX2SC1OH)		
# Item Code Package Description Marketing Start Marketing E	TITANIUM DIOXIDI	E (UNII: 15FIX9V2JP)		
# Item Code Package Description Marketing Start Marketing E				
	Packaging			
	# Item Code	Package Description		Marketing End Date

L	NDC:63824-339- 01	38.4 mL in 1 TUBE; Type 0: Not a Combination Product	08/18/2011	09/01/2024
Μ	larketing	Information		

	eting End Date
OTC monograph final part333D 08/18/2011 09/01/20)24

Revised: 7/2023