

RVR90 REFINE AND PERFECT- zinc oxide
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.

RVR90 Refine and Perfect

Active Ingredients Purpose

Zinc Oxide 12% w/w Sunscreen

Uses

Helps Prevent Sunburn If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

Keep out of reach of children

If product is swallowed, get medical help or contact a poison Control Center right away

Stop use and ask a doctor

- if rash occurs

Warnings

Do not use on:

- damaged or broken skin

When using this product

- keep out of eyes. Rinse with water to remove

For external use only

Directions

- Apply generously 15 minutes before sun exposure and Reapply at least every 2 hours.
- Children under 6 months of age: ask a doctor.

Use a water-resistant sunscreen if swimming or sweating

Sun Protection Measures Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad-Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit your time in the sun, especially from 10 a.m. – 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying



RVR90 REFINE AND PERFECT

zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73122-067
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-067-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	12/20/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	99.9 mL
Part 2	1 BOTTLE	149.9 mL
Part 3	1 BOTTLE	29.9 mL
Part 4	1 BOTTLE	75.1 mL

Part 1 of 4

ULTRA UV PROTECTIVE MINERAL DEFENCE SPF 50

zinc oxide cream

Product Information

Item Code (Source) NDC:73122-068

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARNOSINE (UNII: 8HO6PVN24W)	
ISODODECANE (UNII: A8289P68Y2)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LEVOMENOL (UNII: 24WE03BX2T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PROPANEDIOL (UNII: 5965N8W85T)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRICETEARETH-4 PHOSPHATE (UNII: 69534Y66NO)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
WATER (UNII: 059QF0KOOR)	
CAFFEINE (UNII: 3G6A5W338E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:73122-068-01	99.9 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/20/2021	

Part 2 of 4

ULTRA BRIGHTENING FOAMING CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	COCONUT OIL (UNII: Q9L0073W7L)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	LINOLENIC ACID (UNII: 0RBV727H71)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	GLYCOL STEARATE (UNII: 0324G66D0E)	
INGR	LAURIC ACID (UNII: 1160N9NU9U)	
INGR	LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	LIME OIL, COLD PRESSED (UNII: UZH29XGA8G)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	SODIUM COCOYL GLYCINATE (UNII: XLU9KH03XM)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	COCONUT ACID (UNII: 40U37V505D)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
INGR	PANTHENOL (UNII: VW9CM0067Z)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	

INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	BERGAMOT OIL (UNII: 39W1PKE3JI)	
INGR	GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	CUCUMBER (UNII: YY7C30VXJT)	
INGR	GERANIOL (UNII: L837108USY)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		149.9 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		12/20/2021	

Part 3 of 4

ULTRA A SKIN PERFECTING SERUM MILD

body and hand (excluding shaving preparations) cream

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL)	
INGR	SODIUM PHOSPHATE (UNII: SE337SVY37)	
INGR	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
INGR	BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
INGR	CLIMBAZOLE (UNII: 9N42CW7I54)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	SORBIC ACID (UNII: X045WJ989B)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	DIMETHICONE (UNII: 92RU3N3Y10)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		29.9 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		12/20/2021	

Part 4 of 4

ULTRA MOISTURISER CREAM

lotions, oils, powders, and creams cream

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	PHENYLPROPANOL (UNII: 0F897O3O4M)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	PEG-75 STEARATE (UNII: OT38R0N74H)	
INGR	COCONUT OIL (UNII: Q9L0O73W7L)	
INGR	VANILLIN (UNII: CHI530446X)	
INGR	LINOLENIC ACID (UNII: 0RBV727H71)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	CETETH-20 (UNII: I835H2IHHX)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	WATER (UNII: 059QF0KOOR)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	CHOLESTEROL (UNII: 97C5T2UQ7J)	
INGR	CERAMIDE NP (UNII: 4370DF050B)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
INGR	CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		75.1 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		12/20/2021	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/20/2021	

Labeler - Ultraceuticals US, LLC (117022448)

Revised: 2/2023

Ultraceuticals US, LLC