

RVR90 BRIGHTEN- 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 Brighten

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

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. - 2p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses
- reapply:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

Inactive Ingredients

Allantoin, Bisabolol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Caffeine, Caprylyl Glycol, Caprylyl Methicone, Carnosine, Dimethicone, Isododecane, Lauryl PEG-10 Tris



RVR90 BRIGHTEN

zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73122-061
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-061-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	11/15/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	99.9 mL
Part 2	1 BOTTLE	147.9 mL
Part 3	1 BOTTLE	29.8 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:73122-062
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
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAFFEINE (UNII: 3G6A5W338E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRICETEARETH-4 PHOSPHATE (UNII: 69534Y66NO)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CARNOSINE (UNII: 8HO6PVN24W)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
NIACINAMIDE (UNII: 25X51I8RD4)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LEVOMENOL (UNII: 24WE03BX2T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-062-01	99.9 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Part 2 of 4**ULTRA BRIGHTENING FOAMING CLEANSER**

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

Product Information**Route of Administration** TOPICAL**Other Ingredients**

Ingredient Kind	Ingredient Name	Quantity
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	GERANIOL (UNII: L837108USY)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SODIUM COCOYL GLYCINATE (UNII: XLU9KH03XM)	
INGR	GLYCOL STEARATE (UNII: 0324G66D0E)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	COCONUT OIL (UNII: Q9L0073W7L)	
INGR	SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	COCONUT ACID (UNII: 40U37V505D)	
INGR	BERGAMOT OIL (UNII: 39W1PKE3JI)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	LAURIC ACID (UNII: 1160N9NU9U)	
INGR	LEMON OIL, COLD PRESSED (UNII: I9GRO824LL)	
INGR	GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	CUCUMBER (UNII: YY7C30VXJT)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	

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		11/15/2021	

Part 3 of 4

ULTRA BRIGHTENING SERUM

body and hand (excluding shaving preparations) cream

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	WATER (UNII: 059QF0KO0R)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
INGR	SODIUM SULFITE (UNII: VTK01UQK3G)	
INGR	SODIUM PHOSPHATE (UNII: SE337SVY37)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	MELISSA OFFICINALIS FLOWERING TOP (UNII: 5JQG17B06J)	
INGR	BELLIS PERENNIS WHOLE (UNII: 2HU33I03UY)	
INGR	HYDROXYRESVERATROL (UNII: 6V071CP5CR)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	

Packaging

Item	Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		29.8 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		11/15/2021	

Part 4 of 4

ULTRA BRIGHTENING MOISTURISER CREAM

lotions, oils, powders, and creams cream

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	GERANIUM OIL, ALGERIAN TYPE (UNII: 5Q1I94P4WG)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	STEARETH-20 (UNII: L0Q8IK9E08)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	SANTALUM SPICATUM OIL (UNII: H9LVS6REV4)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	RUMEX OCCIDENTALIS WHOLE (UNII: XS2Y2E2M0T)	
INGR	OCTADECENEDIOIC ACID (UNII: 565ZMT5QRG)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	CETETH-20 (UNII: I835H2IHHX)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	EUCALYPTUS RADIATA LEAF OIL (UNII: SB9A7612BD)	
INGR	CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
INGR	GLYCERYL MONOBEHENATE (UNII: A626UU0W2A)	
INGR	CETYL ALCOHOL (UNII: 936JST6JCN)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
INGR	PEG-75 STEARATE (UNII: OT38R0N74H)	

INGR	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
INGR	ORANGE OIL, COLD PRESSED (UNII: AKN3KSD11B)	
INGR	BERGAMOT OIL (UNII: 39W1PKE3JI)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
INGR	YLANG-YLANG OIL (UNII: 8YOY78GNNX)	
INGR	PHENYLPROPANOL (UNII: 0F897O3O4M)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	SQUALANE (UNII: GW89575KF9)	
INGR	METHYLPROPANEDIOL (UNII: N8F53B3R4R)	

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		11/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/15/2021	

Labeler - Ultraceuticals US, LLC (117022448)