

**RVR90 FIRM- zinc oxide
Ultracuticals 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 Firm

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

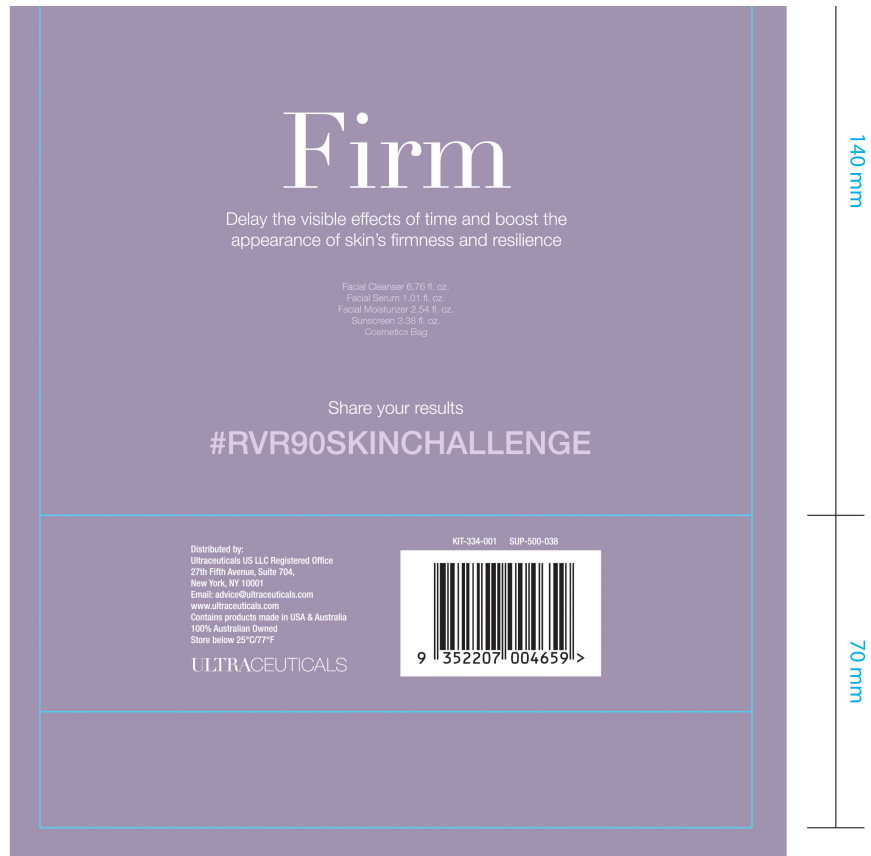
Directions

- 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 FIRM

zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73122-065
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-065-01	1 in 1 KIT; Type 1: Convenience Kit of Co-Package	01/03/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	99.9 mL
Part 2	1 BOTTLE	199 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:73122-066

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
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
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)	
TRICETARETH-4 PHOSPHATE (UNII: 69534Y66NO)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
WATER (UNII: 059QF0KO0R)	
CAFFEINE (UNII: 3G6A5W338E)	

Packaging

Marketing Start Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73122-066-01	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 BALANCING GEL CLEANSER

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

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
INGR	HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
INGR	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	FORMIC ACID (UNII: 0YIW783RG1)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	PANTHENOL (UNII: WW9CM0067Z)	
INGR	CUCUMBER (UNII: YY7C30VXJT)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
INGR	OATMEAL (UNII: 8PI54V663Y)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	

INGR	LAURETH-4 (UNII: 6HQ855798J)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	SORBIC ACID (UNII: X045WJ989B)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		199.9 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		01/03/2022	

Part 3 of 4

ULTRA C FIRMING SERUM

body and hand (excluding shaving preparations) lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ASCORBIC ACID (UNII: PQ6CK8PD0R)	
INGR	CITRAL (UNII: T7EU009VPP)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
INGR	PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	LAVENDER OIL (UNII: ZBP1YXW0H8)	
INGR	YLANG-YLANG OIL (UNII: 8YOY78GNNX)	
INGR	CHAMAEMELUM NOBILE FLOWER OIL (UNII: UB27587839)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	DEXTRAN 1 (UNII: I8LHQ0D645)	
INGR	PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	
INGR	LINALOOL, (+/-)- (UNII: D81QY6I88E)	
INGR	GERANIOL (UNII: L837108USY)	
INGR	.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
INGR	DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	

INGR	ANOGEISSUS LEOCARPUS BARK (UNII: U5TP1X38RH)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	CAPROOYL TETRAPEPTIDE-3 (UNII: LZ10HJ3K2R)	
INGR	ALCOHOL (UNII: 3K9958V90M)	
INGR	SODIUM PHOSPHATE (UNII: SE337SVY37)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
INGR	MENYANTHES TRIFOLIATA LEAF (UNII: GYG64DIH9P)	
INGR	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
INGR	SODIUM SULFITE (UNII: VTK01UQK3G)	
INGR	MANDARIN OIL (UNII: NJO720F72R)	

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		01/03/2022	

Part 4 of 4

ULTRA HYDRATING LOTION

lotions, oils, powders, and creams lotion

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	DECYL OLEATE (UNII: ZGR06DO97T)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	LINOLENIC ACID (UNII: 0RBV727H71)	
INGR	SOYBEAN OIL (UNII: 241ATL177A)	
INGR	TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	OLIVE OIL DECYL ESTERS (UNII: 3AQ222F18X)	
INGR	SQUALENE (UNII: 7QWM220FJH)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
INGR	AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	CETEARETH-12 (UNII: 7V4MR24V5P)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	CHOLESTEROL (UNII: 97C5T2UQ7J)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	PHENYLPROPANOL (UNII: 0F897O3O4M)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	CETYL PALMITATE (UNII: 5ZA2S6B08X)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	BENZOIC ACID (UNII: 8SKNOB0MIM)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	CERAMIDE NP (UNII: 4370DF050B)	
INGR	METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
INGR	DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
INGR	WATER (UNII: 059QF0KOOR)	
INGR	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		75.1 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		12/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/03/2022	

Labeler - Ultraceuticals US, LLC (117022448)

Revised: 2/2023

Ultraceuticals US, LLC