

STARTER SET OILY/NORMAL SKIN- zinc oxide ULTRACEUTICALS PTY LIMITED

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.

Starter Set Oily/Normal Skin

Active Ingredients Purpose

Zinc Oxide 12% w/w Sunscreen

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 or irritation develops and lasts.

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
- **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
 - 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(trimethylsiloxy) Silylethyl Dimethicone, Lauryl PEG-8 Dimethicone, Methylpropanediol, Niacinamide, Octyldodecyl Neopentanoate, PEG-10, Phenylpropanol,

Starter Set Oily/Normal Skin

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ULTRACEUTICALS

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STARTER SET OILY/NORMAL SKIN

zinc oxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10028-020
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10028-020-01	1 in 1 PACKAGE, COMBINATION; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/01/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	100 mL in 100
Part 2	1 BOTTLE	200 mL
Part 3	1 BOTTLE	30 mL in 30
Part 4	1 BOTTLE	75 mL in 100

Part 1 of 4

ULTRA PROTECTIVE PROTECTIVE MINERAL DEFENCE SPF 50

zinc oxide cream

Product Information

Item Code (Source)	NDC:10028-021
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
ALLANTOIN (UNII: 344S277G0Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CARNOSINE (UNII: 8HO6PVN24W)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CAFFEINE (UNII: 3G6A5W338E)	
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PHENYLPROPANOL (UNII: 0F897O3O4M)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPANEDIOL (UNII: 5965N8W85T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TRICETARETH-4 PHOSPHATE (UNII: 69534Y66NO)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
WATER (UNII: 059QF0KO0R)	
POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10028-021-01	100 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2020	

Part 2 of 4

ULTRA BALANCING GEL CLEANSER

other skin care preparations gel

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	FORMIC ACID (UNII: 0YIW783RG1)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	LAURETH-4 (UNII: 6HQ855798J)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
INGR	EDETATE SODIUM (UNII: MP1J8420LU)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	OATMEAL (UNII: 8PI54V663Y)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
INGR	SODIUM LAUROYL SARCOSINATE (UNII: 632GS99618)	
INGR	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	

INGR	MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
INGR	SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	SORBIC ACID (UNII: X045WJ989B)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	SODIUM BENZOATE (UNII: OJ245FE5EU)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	CUCUMBER (UNII: YY7C30VXJT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		200 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		03/01/2020	

Part 3 of 4

ULTRA B2 HYDRATING SERUM

lotions, oils, powders, and creams cream

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	NIACINAMIDE (UNII: 25X51I8RD4)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	PROPANEDIOL (UNII: 5965N8W85T)	
INGR	WATER (UNII: 059QF0KO0R)	
INGR	PANTHENOL (UNII: WW9CM0O67Z)	
INGR	BENZYL ALCOHOL (UNII: LKG8494WBH)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	CUCUMBER (UNII: YY7C30VXJT)	
INGR	TREHALOSE (UNII: B8WCK70T7I)	

INGR	SALICYLIC ACID (UNII: O414PZ4LPZ)	
INGR	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
INGR	SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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		03/02/2020	

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	CHOLESTEROL (UNII: 97C5T2UQ7J)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
INGR	CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
INGR	TOCOPHEROL (UNII: R0ZB2556P8)	
INGR	AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
INGR	CETYL PALMITATE (UNII: 5ZA2S6B08X)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
INGR	DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
INGR	DECYL OLEATE (UNII: ZGR06DO97T)	
INGR	TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
INGR	LACTIC ACID (UNII: 33X04XA5AT)	
INGR	OLIVE OIL DECYL ESTERS (UNII: 3AQ222F18X)	
INGR	SQUALENE (UNII: 7QWM220FJH)	

INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	UREA (UNII: 8W8T17847W)	
INGR	LINOLEIC ACID (UNII: 9KJL21T0QJ)	
INGR	SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
INGR	LINOLENIC ACID (UNII: 0RBV727H71)	
INGR	ALOE VERA LEAF (UNII: ZY81Z83H0X)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	GLYCERIN (UNII: PDC6A3C00X)	
INGR	BENZOIC ACID (UNII: 8SKN0B0MIM)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	XANTHAN GUM (UNII: TTV12P4NEE)	
INGR	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
INGR	SOYBEAN OIL (UNII: 241ATL177A)	
INGR	CETEARETH-12 (UNII: 7V4MR24V5P)	
INGR	CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
INGR	SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
INGR	PHENYLPROPANOL (UNII: 0F897O3O4M)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	MALTODEXTRIN (UNII: 7CVR7L4A2D)	
INGR	SODIUM LACTATE (UNII: TU7HW0W0QT)	
INGR	LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
INGR	CERAMIDE NP (UNII: 4370DF050B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		75 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		03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/01/2020	

Labeler - ULTRACEUTICALS PTY LIMITED (744068995)