SPF 50 MOISTURIZING SUNSCREEN BROAD SPECTRUM- octinoxate, zinc oxide lotion
GATE THERAPEUTICS

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.

SPF 50 Moisturizing Sunscreen

Active Ingredients	Purpose
Octinoxate 6%, Zinc Oxide 12%	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
For External Use Only
Do not use on damaged or broken skin
When using this product keep out of eyes. Rinse with water to remove.

Directions
• Apply liberally 15 minutes before sun exposure

• Reapplyat least every 2 hours
• 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 15 or higher and other sun protection measures including:
• Limit time in the sun, especially from 10a.m. – 2p.m.
• Wear long-sleeve shirts, pants, hats, and sunglasses
• Children under six months consult a physician

Inactive ingredients Water, Polysorbate 60, Coconut Alkanes, C12-15 Alkyl Benzoate, Octyldodecyl Neopentanoate, Cetearyl Alcohol, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, PEG-100 Stearate, Bisabolol, Coffea Arabica (Coffee) Seed Oil, Pentylene Glycol, Tetrahexyldecyl Ascorbate, Xanthophyll, Ascorbyl Palmitate, Tocopherol, Beta-Carotene, Coco-Caprylate/Caprate, Folic Acid, Carthamus Tinctorius (Saffower) Seed Oil, Solanum Lycopersicum (Tomato) Seed Oil, Tocopheryl Acetate, Vaccinium Myrtillus (Bilberry) Fruit Extract, Argania Spinosa Kernel Oil, Dimethicone, Dipotassium Phosphate, Hydrogenated Lecithin, Potassium Phosphate, Zea Mays (Corn) Oil, Polyhydroxystearic Acid, Alcohol, Butylene Glycol, Xanthan Gum, Disodium EDTA, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Citric Acid, Dehydroacetic Acid, Benzyl Alcohol

SPF 50+

Moisturizing Sunscreen

Broad Spectrum Daily Use

1Fl Oz/30 mL

SPF 50 MOISTURIZING SUNSCREEN BROAD SPECTRUM

octinoxate, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72274-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
LEVOMENOL (UNII: 24WE03BX2T)	
ARABICA COFFEE OIL (UNII: IK55HKE887)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
LUTEIN (UNII: X72A60C9MT)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
FOLIC ACID (UNII: 935E97BOY8)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
TOMATO SEED OIL (UNII: 7N87T9C06T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BILBERRY (UNII: 9P2U39H18W)	
ARGAN OIL (UNII: 4V59G5UW9X)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIBASIC POTASSIUM PHOSPHATE (UNII: CI71S98N1Z)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
CORN OIL (UNII: 8470G57WFM)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72274-002-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	05/04/2018	
2	NDC:72274-002-02	90 mL in 1 TUBE; Type 0: Not a Combination Product	05/04/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/04/2018	

Labeler - GATE THERAPEUTICS (081159085)

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