MANS BEST FRIEND- octinoxate homosalate octisalate titanium dioxide cream Jaxon Lane, Inc.

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.

MAN'S BEST FRIEND

Active ingredients

Octinoxate, Homosalate, Octisalate, titanium dioxide

Purpose: Sunscreen

Inactive Ingredients

Water, Pentylene Glycol, Methylpropanediol, Caprylyl Methicone, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Isononyl Isononanoate, Ethylhexyl Triazone, Lauryl Methacrylate/Glycol Dimethacrylate Crosspolymer, Cyclopentasiloxane, Phenoxyethanol, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Aluminium Hydroxide, Stearic Acid, Dimethicone/Vinyl Dimethicone Crosspolymer, Tocopheryl Acetate (Vitamin E), Sorbitan Isostearate, Ammoniumacryloyldimethyl Taurate/VP Copolymer, Allantoin, Polysorbate 80, Butylene Glycol, Sorbitan Oleate, BHT Xanthan Gum, Biosaccharide Gum-4, Sodium Hyaluronate, Moringa Seed Oil, Ethylhexylglycerin, Green Tea Extract, Licorice Root Extract, Panax Ginseng Root Extract, Fragrance

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.

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. **Stop use and ask a doctor if** rash occurs. **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Apply ©liberally 15 minutes before sun exposure. Reapply every 2 hours and after swimming. Children under 6 months: Ask a doctor.

Sun Protection Measures: Sun exposure increases your risc of skin cancer and early skin aging. Use a sunscreen with a minium Broad Spectrum SPF15+ Limit time in the Sun, especially from 10 am - 2pm, wear hats, sunglasses, long-sleeve, clothing and pants.

Other Information:

Protect this product from excessive heat and direct sun.

PRINCIPAL DISPLAY PANEL



MANS BEST FRIEND

octinoxate homosalate octisalate titanium dioxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:73072-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) OCTINOXATE 7 g in 100 mL HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) 3 g in 100 mL HOMOSALATE OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) OCTISALATE 3 g in 100 mL TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP) TITANIUM DIO XIDE 1.5 g in 100 mL

Inactive Ingredients Ingredient Name	Strength
•	Strengti
WATER (UNII: 059QF0KO0R)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
METHYLPRO PANEDIOL (UNII: N8 F53B3R4R)	
CAPRYLYL TRISILO XANE (UNII: Q95M2P1KJL)	
BEMOTRIZINOL (UNII: PWZ1720 CBH)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PHENO XYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (4000000 MW) (UNII: 1DXE3F3OZX)	
ISO HEXADECANE (UNII: 9 18 X10 UF1E)	
ALUMINUM HYDRO XIDE (UNII: 5QB0 T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIMETHICO NE/VINYL DIMETHICO NE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
.ALPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
AMMO NIUM ACRYLO YLDIMETHYLTAURATE/VP CO PO LYMER (UNII: W59 H9 29 6 ZG)	
ALLANTO IN (UNII: 344S277G0Z)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
BUTYLATED HYDRO XYTOLUENE (UNII: 1P9 D0 Z171K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BIO SACCHARIDE GUM-4 (UNII: 9XRL057X90)	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)	
MORINGA OLEIFERA SEED OIL (UNII: REM6 A5QMC0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	

l	Packaging							
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date				
l	1 NDC:73072-001-01	60 mL in 1 TUBE; Type 0: Not a Combination Product	05/01/2019					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part352	05/01/2019				

Registrant - Jaxon Lane, Inc. (114672469)

Establishment							
Name	Address	ID/FEI	Business Operations				
EYESOME. Co.,Ltd.		557795360	manufacture(73072-001)				

Revised: 4/2019 Jaxon Lane, Inc.