PRO-TECT SUNSCREEN FOR PROFESSIONALS- meradimate, octinoxate, octisalate, oxybenzone lotion Bio-Medical & Pharmaceutical Manufacturing Corporation

Active ingredients

Meradimate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 5.0%

Purpose

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.

Warnings

• For external use only. • Do not use on damaged or broken skin. • Stop use and ask a doctor if rash occurs. • When using this product keep out of eyes. Rinse with water to remove. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months: 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 protections measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats, and sun-glasses

Other Information

• protect this product from excessive heat and direct sun.

Inactive Ingredients

Aloe Vera Leaf, Benzyl Alcohol, C18-36 Acid Glycol Ester, Carbomer Copolymer Type B

(Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Cetyl Dimethicone 45, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Eicosyl Povidone, Iodopropynyl Butylcarbamate, Lanolin, Mineral Oil, Stearic Acid, Talc, Trolamine, Water.

Questions or Comments

281-835-8051 | Bio-Med & Pharm. Mfg. Corp.

Package label

SUNSCREEN FOR PROFESSIONALS

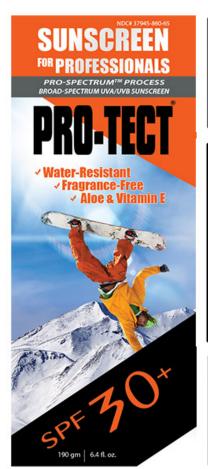
PRO-SPECTRUM PROCESS BROAD-SPECTRUM UVA/UVB SUNSCREEN

PRO-TECT

Water-Resistant

Fragrance-Free

Aloe & vitamin E



DRUG FACTS

Active Ingredients

Purpose

Meradimate 5.0%, Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 5.0%...

.....Sunsc

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.

Drug facts (continued)

Warnings

• For external use only. • Do not use on damaged or broken skin. • Stop use and ask a doctor if rash occurs. • When using this product keep out of eyes. Rinse with water to remove. • Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

apply liberally 15 minutes before sun exposure • reapply: after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months: 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 protections measures including: • limit time in the sun, especially from 10 a.m.-2 p.m. • wear long-sleeved shirts, pants, hats, and sun-glasses

Other Information

protect this product from excessive heat and direct sun.

.

▶ Drug facts (continued)

Inactive Ingredients

Aloe Vera Leaf, Benzyl Alcohol, C18-36 Acid Glycol Ester, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Cetyl Dimethicone 45, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dL-Alpha Tocopheryl Acetate, Eicosyl Povidone, Iodopropynyl Butylcarbamate, Lanolin, Mineral Oil, Stearic Acid, Talc, Trolamine, Water.

Questions or Comments : 281-835-8051 | Bio-Medical & Pharm Mfg. Corp.

PRO-TECT SUNSCREEN FOR PROFESSIONALS

meradimate, octinoxate, octisalate, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37945-860
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g	
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	50 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	50 mg in 1 g	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
LANOLIN (UNII: 7EV65EAW6H)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MINERAL OIL (UNII: T5L8T28FGP)	
TALC (UNII: 7SEV7J4R1U)	
TROLAMINE (UNII: 903K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	

Packaging				
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:37945- 860-64	100 g in 1 CONTAINER; Type 0: Not a Combination Product	02/05/2015	
2	NDC:37945- 860-65	190 g in 1 CONTAINER; Type 0: Not a Combination Product	02/05/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	11/01/1980	

Labeler - Bio-Medical & Pharmaceutical Manufacturing Corporation (072186356)

Establishment			
Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(37945-860)

Revised: 12/2023 Bio-Medical & Pharmaceutical Manufacturing Corporation