

PRO-TECT SPORTS SUNSCREEN- meradimate, octinoxate, octisalate, oxybenzone lotion

Bio-Medical & Pharmaceutical Manufacturing Corporation

Active ingredients

Meradimate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 3.0%

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 protection 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, Carbomer Copolymer Type B (Allyl Pentaerythritol Crosslinked), Cetyl Alcohol, Cetyl Dimethicone 45, Diazolidinyl Urea, Diethanolamine Cetyl Phosphate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Stearic Acid, Talc, Trolamine, Water.

Questions or Comments

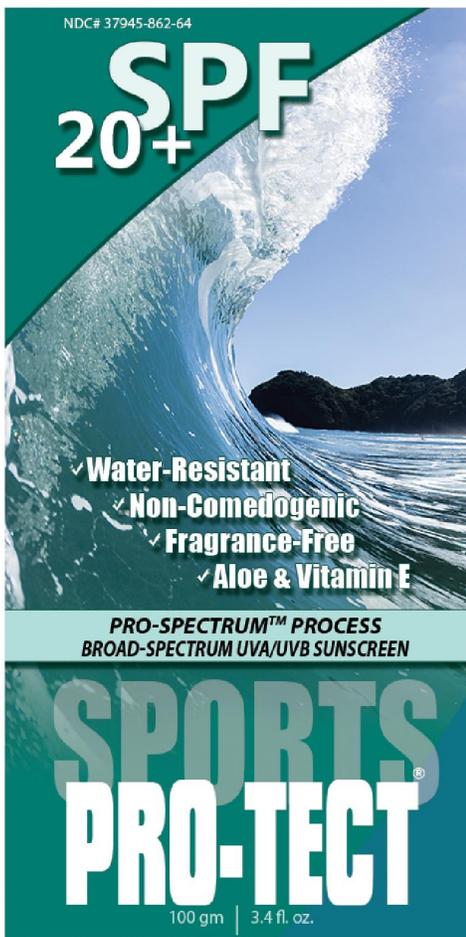
281-835-8051

Bio-Med & Pharm. Mfg. Corp.

Package label

pro-TECT SPF 20

3.4 oz



DRUG FACTS

Active Ingredients	Purpose
Meradimate 5.0%, Octinoxate 7.5%.....	Sunscreen
Octisalate 5.0%, Oxybenzone 3.0%.....	Sunscreen

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► Drug facts (continued)

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► Drug facts (continued)

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

PRO-TECT SPORTS SUNSCREEN

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37945-862
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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL DIMETHICONE 45 (UNII: IK315POC44)	
DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-862-64	100 g in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/27/2015	

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

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 12/2023

Bio-Medical & Pharmaceutical Manufacturing Corporation