

PRO-TECT SUNSCREEN FOR PROFESSIONALS- meradimate, octinoxate, octisalate, oxybenzone lotion

Bio-Medical & Pharmaceutical Manufacturing Corporation

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.

Active ingredients

Meradimate 5.0%

Octinoxate 7.5%

Octisalate 5.0%

Oxybenzone 5.0%

Purpose

Sunscreen

Uses

• Pro-Tect® SPF 30+ Broad-Spectrum UVA & UVB protection. • Helps prevent sunburn. • Retains a SPF of 30+ after 80 minutes of activity in water or perspiring. • Provides high protection against sunburn and tanning. • For skin highly sensitive to sunburn.

Warnings

• External use only. • When using this product, keep out of eyes. • Rinse with water to remove. • Stop use and ask a doctor if rash or irritation develops and lasts. • Do not use if sensitive to any of the ingredients or their related compounds.

KEEP OUT OF REACH OF CHILDREN

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Directions

•Apply this product topically to affected areas and allow to dry without rubbing. •Use up to 3 times daily. •Use only as directed.

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.

Other Information

• Daily usage of Pro-Tect® SPF 30+ may help reduce the chance of premature aging of the skin due to overexposure to the sun. • This product provides more than 30 times your natural protection against

sunburn. • Very Water Resistant UVA & UVB Broad-Spectrum Protection. • This product may stain light colored fabrics if washed with bleach. Wash clothing without bleach to remove safely.

Questions or Comments

Bio-Medical & Pharm. Mfg. Corp., 4311 South Dr., Houston, TX 77053-4820, 281-835-8051, M-F 8AM-5PM, www.protectsunscreen.com

Package label

SUNSCREEN FOR PROFESSIONALS

PRO-SPECTRUM PROCESS BROAD-SPECTRUM UVA/UVB SUNSCREEN

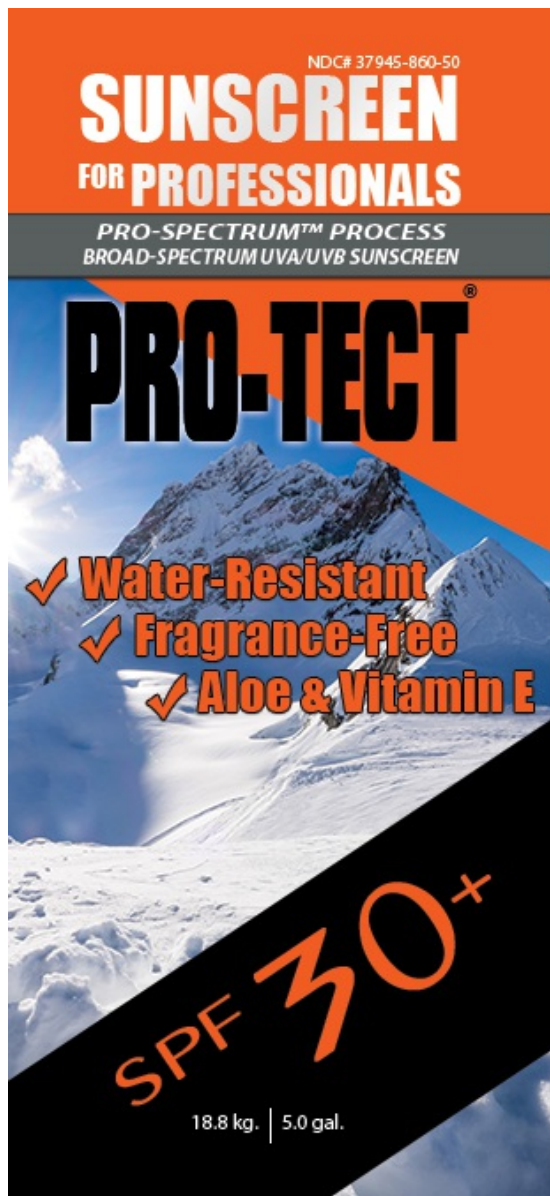
PRO-TECT

Water-Resistant

Fragrance-Free

Aloe & vitamin E

SPF 30+



18.8 kg /5 gal.

Bulk Only - Not For Retail Sale

DRUG FACTS

Pro-Tect® SPF 30+ Sunscreen Broad-Spectrum UVA/UVB Protection & Moisturizing Lotion

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

Uses - Pro-Tect® SPF 30+ Broad-Spectrum UVA & UVB protection. • Helps prevent sunburn. • Retains a SPF of 30+ after 80 minutes of activity in water or perspiring. • Provides high protection against sunburn and tanning. • For skin highly sensitive to sunburn.

Warnings - External use only. • When using this product, keep out of eyes. • Rinse with water to remove. • Stop use and ask a doctor if rash or irritation develops and lasts. • Do not use if sensitive to any of the ingredients or their related compounds.

KEEP OUT OF REACH OF CHILDREN

Directions - Apply liberally and evenly on all exposed areas 20-30 minutes before exposure to the sun and as needed. • Children under 6 months of age: ask a doctor.

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.

Other Information - Daily usage of Pro-Tect® SPF 30+ may help reduce the chance of premature aging of the skin due to overexposure to the sun. • This product provides more than 30 times your natural protection against sunburn. • Very Water Resistant UVA & UVB Broad-Spectrum Protection. • This product may stain light colored fabrics if washed with bleach. Wash clothing without bleach to remove safely.

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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: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	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: 9O3K93S3TK)				
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)				
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)				
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37945-860-50	1880 g in 1 CONTAINER; Type 0: Not a Combination Product	05/15/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	05/15/2015		

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

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

Revised: 2/2020

Bio-Medical & Pharmaceutical Manufacturing Corporation