PRO-TECT SPORTS SUNSCREEN SPF 20- meradimate, octinoxate, octisalate, oxybenzone lotion
ABBE Laboratories, 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.

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 10a.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 Phospate, dl-Alpha Tocopheryl Acetate, Iodopropynyl Butylcarbamate, Stearic Acid, Talc, Trolamine, Water.

Questions or Comments

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Package Label

NDC#68605-8640-8

Drug Facts (continued)

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?
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15530-8

A-CUTE DERM®
medical skincare

PRO-TECT®

SPF 20
SUNSCREEN

8.0 FL OZ (236.6 ml)

Drug Facts

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

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PRO-TECT SPORTS SUNSCREEN SPF 20

meradimate, octinoxate, octisalate, oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68605-8640
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 mL
MERADIMATE (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	30 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

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:68605-8640-4	118.3 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2022	
2	NDC:68605-8640-8	236.6 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2022	
3	NDC:68605-8640-2	946.4 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/01/2022	

Labeler - ABBE Laboratories, Inc. (781745286)

Establishment

Name	Address	ID/FEI	Business Operations
Bio-Medical & Pharmaceutical Manufacturing Corporation		072186356	manufacture(68605-8640)

Revised: 11/2022 ABBE Laboratories, Inc.