BE SMART GET PREPARED SUNSCREEN- sunscreen ointment Total Resources International 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.

Be Smart Get Prepared Sunscreen

Active ingredient Purpose

Homosalate (6.0%)

Octinoxate (7.5%)

Octisalate (5.0%)

Oxybenzone (5.0%).....Sunscreens

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection
- for skin highly sensitive to sunburn

Skin cancer/skin aging alert: spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early aging skin.

For external use only.

Stop use and ask a doctor if

• rash occurs.

Do not use • on damaged or broken skin.

Stop use, ask a doctor if

rash occurs

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 at least every two hours
- use a water resistant sunscreen if swimming or sweating
- children under 6 months: ask a doctor

Other Information

• protect this product in this container from excessive heat and direct sun

Inactive ingredients

cetyl alcohol, ganex P-904, germaben II, petrolatum, polyoxyl 40 stearate, polysorbate 60, purified water, sorbitan monostearate, tetrasodium EDTA, titanium dioxide, xanthan





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sunscreen ointment

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55550-950
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 mg in 1 g	

OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	5 mg in 1 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6 mg in 1 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
POLYSORBATE 60 (UNII: CAL22UVI4M)		
XANTHAN GUM (UNII: TTV12P4NEE)		
POVIDONE K30 (UNII: U725QWY32X)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)		
EDETATE SODIUM (UNII: MP1J8420LU)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
WATER (UNII: 059QF0KO0R)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
PETROLATUM (UNII: 4T6H12BN9U)		
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:55550-950- 02	1.5 g in 1 POUCH; Type 0: Not a Combination Product	01/01/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2023	

Labeler - Total Resources International Inc. (790160535)

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