

SUNSCREEN CREAM SPF 30- homosalate, octyl methoxycinnamate, benzophenone-3, titanium dioxide cream

Davemed Healthcare Co., Ltd

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.

Sunscreen Cream SPF 30

Active Ingredients

Active ingredients Purpose

Homosalate.....Sunscreen

Octyl methoxycinnamate.....Sunscreen

Benzophenone-3.....Sunscreen

Titanium dioxide.....Sunscreen

Purpose

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Homosalate.....Sunscreen

Octyl methoxycinnamate.....Sunscreen

Benzophenone-3.....Sunscreen

Titanium dioxide.....Sunscreen

Uses

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- Helps prevent sunburn
- Higher SPF gives more protection
- For skin highly sensitive to sunburn

For external use only

When using this product

- Keep out eyes. Rinse with water to remove

Stop use and ask a doctor if rash or irritation develops and lasts

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children

- if swallowed, contact a poison control center or doctor right away

Directions

- Apply liberally before sun exposure and as needed
- Children under 6 months of age: ask a doctor

Inactive ingredients

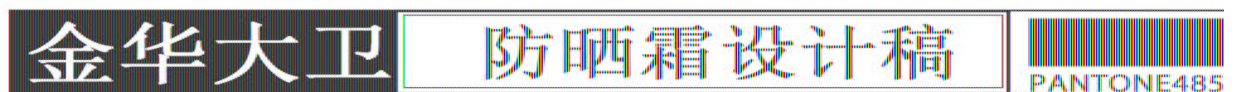
Water, Cetearyl Alcohol, Glycerin monostearate Gctt, Propylparaben, Methylparaben, glycerol, EDTA-2NA, Vinylchloride-methylacrylate, copolymer, Methylisothiazolinone

Other Information

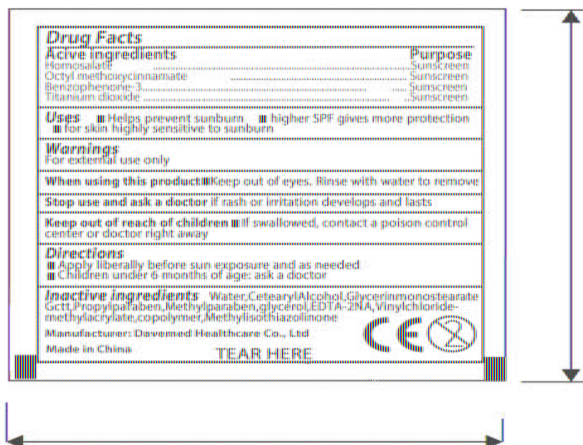
Other Information

Store at room temperature

Principal Display Panel



请注意：红色潘通色号是485C



SUNSCREEN CREAM SPF 30

homosalate, octyl methoxycinnamate, benzophenone-3, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70897-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4 g in 100 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	3 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETIC ACID (UNII: 9G34HU7RV0)	
VINYL CHLORIDE (UNII: WD06X94M2D)	
GLATIRAMER ACETATE (UNII: 5M691HL4BO)	
DIGLYCERIN MONOSTEARATE (UNII: E3XK1VOF1Y)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-008-01	6 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2019	

Labeler - Davemed Healthcare Co., Ltd (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-008)

