5281 SUNSCREEN- octocrylene, titanium dioxide, octisalate lotion
Innovation Specialties

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.

5281 sunscreen

Drug Facts

Active Ingredient

Octocrylene 9%

Titanium dioxide 7%

Octisalate 5%

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
When using this product keep out of eyes. Rinse with water to remove.
Stop use and ask a doctor if rash occurs

Keep out of reach of children. If products is swallowed, get medical help or contact a Poison Control Center right away.

Directions

•apply liberally 15 minutes before sun exposure

•reapply:

- •after 40 minutes of swimming or sweating
- •immediately after towel drying
- •at least every 2 hours

•**Sun Protection Measure.** 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 of 15 higher and other sun protection measures including:

- •limit time in the sun, especially from 10 a.m.-2 p.m.
- •wear long-sleeve shirts, pants, hats, and sunglasses

•children under 6 months: Ask a doctor

Inactive ingredients

Water, C12-15 Alkyl Benzoate, Isopropyl Myristate, Caprylic/Capric Triglyceride, Cetearyl Alcohol, CETETH-25, Glyceryl Stearate, Glycerin, Dmdm Hydantoin, Methyl Paraben, Propylparaben, Fragrance

Other information

•protect this product from excessive heat and direct sun

NDC (76138-213-05)

DIN 02448890
Made in China for Innovation line.
Los Angeles CA 90066
Questions or Comments?
Call:1-855-755-5346

Broad Spectrum SPF 30 Sunscreen Lotion

Packaging


Broad Spectrum SPF30 Sunscreen Lotion
NetWt 15ml/0.5oz

Drug Facts

Active Ingredient		Purpose
Octocrylene	9%	Sunscreen
Titanium dioxide	7%	
Octisalate	5%	

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
When using this product keep out of eyes. Rinse with water to remove
Stop use and ask a doctor if rash occurs
Keep out of reach of children. If products is swallowed, get medical help or contact a Poison Control Center right away.

Peel here for continued drug facts ▼


Drug Facts *(continued)*

Directions
•apply liberally 15 minutes before sun exposure
•reapply:
•after 40 minutes of swimming or sweating
•immediately after towel drying
•at least every 2 hours
•**Sun Protection Measure.** 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 spectrun SPF of 15 higher and other sun protection measures including:
•limit time in the sun,especially from 10 a.m.-2 p.m.
•wear long-sleeve shirts,pants,hats, and sunglasses
•children under 6 months:Ask a doctor


Drug Facts *(continued)*

Inactive ingredients
Water,C12-15 Alkyl Benzoate,Isopropyl Myristate, Caprylic/Capric Triglyceride,Cetearyl Alcohol, CETETH-25,Glyceryl Stearate,Glycerin, Dmdm Hydantoin,Methyl Paraben, Propylparaben,Fragrance

Other information
•protect this product from excessive heat and direct sun

NDC (76138-213-05)
DIN 02448890
Made in China for
Innovation line.
Los Angeles CA 90066
Questions or Comments?
Call:1-855-755-5346

5281 SUNSCREEN

octocrylene, titanium dioxide, octisalate lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76138-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-25 (UNII: 5KLY4IOG20)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:76138-213-05	15 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2018	

Labeler - Innovation Specialties (030837314)

Revised: 8/2017 Innovation Specialties