

GOLFERS SKIN BROAD SPECTRUM SPF 30 PLUS SUNSCREEN - octinoxate, oxybenzone, titanium dioxide, zinc oxide cream

Skin Alive, 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.

Golfers Skin Broad Spectrum SPF 30+ Sunscreen

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Active Ingredients

Octinoxate 7.5%

Oxybenzone 3.45%

Titanium Dioxide 1%

Zinc Oxide 1.95%

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

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply generously 15 mins before sun exposure.

Reapply:

- * After 40 minutes of swimming or sweating.
- * Immediately after towel drying
- * At least every 2 hours

Sun Protections Measure. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use and sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:

- * Limit time in the sun, especially from 10am-2pm
- * Wear long-sleeve shirts, pants, hats and sunglasses
- * Children under 6 months: Ask a Doctor

Inactive Ingredients

Aloe Vera Gel, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cyclomethicone, Deionised Water, Fragrance, Glyceryl Monostearate, Phenoxyethanol, Polysorbate 60, PVP ejcosene, Retinol Palminate, Sorbitan Monostearate, Tocopherol Acetate, UMF 18 Manuka Honey

spf 30+

very water/sweat resistant

broad spectrum

UVA/UVB Protection

Golfersskin Sunscreen

Proven in Extreme New Zealand conditions

manuka honey UMF 18

CONTAINS NO NANOPARTICLES - AMINOBENZOIC ACID (PABA)-FREE

Representative Product Labeling

broad spectrum **Spf30+**

golfer**skin**TM sunscreen

WATER RESISTANT
(80 MINUTES)

1.35 fl oz (40ml)

manuka honey UMF 18

**CONTAINS NO NANOPARTICLES -
AMINO BENZOIC ACID (PABA) - FREE**

**Golfersskin SPF 30+ Sunscreen, VERY WATER/SWEAT
RESISTANT, BROAD SPECTRUM, UVA/UVB PROTECTION.**

Drug Facts

Active Ingredients	Purpose
Octinoxate 7.5% Oxybenzone 3.45% Titanium Dioxide 1% Zinc Oxide 1.95%	} ... Sunscreen

Uses

• Helps prevent sunburn.
• If used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer & 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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15mins before sun exposure.
- Reapply:
 - After 40 minutes of swimming or sweating.
 - Immediately after towel drying.
 - At least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer & early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher & other sun protection measures including:
 - Limit time in the sun, especially from 10am-2pm.
 - Wear long-sleeve shirts, pants, hats & sunglasses.
 - Children under 6 months: Ask a Doctor.

Inactive Ingredients

AloeVera Gel, Caprylic/Capric Triglyceride, Cetearyl Alcohol, Cyclomethicone, Deionised water, Fragrance, Glyceryl Monostearate, Phenoxyethanol, Polysorbate 60, PVP/Eicosene, Retinol Palmitate, Sorbitan Monostearate, Tocopherol Acetate, UMF 18 Manuka Honey.



To report a serious
adverse event,
contact:
1-800-332-1088

MADE IN NZ

golferskin**
alive**

EXPIRES :

LOT NUMBER :

www.golfersskin.co

DIST. BY Quiver Dist., Bend Oregon, USA 97701
AS/ANZ STANDARD 2604:1998

1.35 fl oz (40ml)

GOLFERS SKIN BROAD SPECTRUM SPF 30 PLUS SUNSCREEN

octinoxate, oxybenzone, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75916-4020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	34.5 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	19.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0K00R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HONEY (UNII: Y9H1V576FH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75916-4020-4	125 mL in 1 TUBE		
2	NDC:75916-4020-1	1 in 1 BOX		
2		40 mL in 1 TUBE		
3	NDC:75916-4020-3	1000 mL in 1 BOTTLE		
4	NDC:75916-4020-5	2000 mL in 1 BOTTLE		
5	NDC:75916-4020-2	5 mL in 1 PACKET		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/31/2011	

Labeler - Skin Alive, Ltd. (593384746)

Registrant - Skin Alive, Ltd. (593384746)

Revised: 1/2015

Skin Alive, Ltd.