PROTETOR SOLAR GRIP ACTION FPS 40- octinoxate, octisalate, octocrylene, avobenzone cream Alfa Distribution and Imports

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.

Protetor Solar Grip Action FPS 40

ACTIVE INGREDIENTS

Octinoxate 7.50%

Octisalate 5.00%

Octocrylene 5.00%

Avobenzone 3.00%

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 consult physician

*if irritation or rash develops.

Keep out of reach of children.

* If product is swallowed, get medical attention or contact poison control center immediately.

DIRECTIONS:

* Apply liberally 15-minutes before sun exposure.

* Reapply: - At least every two-hours.

* Immediately after swimming, sweating or towel drying. SUN PROTECTION MEASURES: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscren with broad spectrum protection and an SPF rating of 15 or higher, along with other sun protection measures including:

- Limit time in the sun, especially between 10am and 2pm.

- -Wear long sleeve shirts, pants, hats and sunglasses.
- For children under 6-months, consult a physician.

OTHER INGREDIENTS:

Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Citric Acid, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, PEG-100 Stearate, Phenoxyethanol, Polysorbate-80, Styrene/Acrylates Copolymer, Tocopheryl Acetate (Vitamin E), Zemea (Corn) Propanediol.

OTHER INFORMATION:

*Protect this product from excessive heat and direct sunlight.

Package Labeling:

ACTIVE INGREDIENTS	PUR	POSE	
Octinoxate Octisalate Octocrylene Avobenzone	7.50% 5.00% 5.00% 3.00%	Sunscreen Sunscreen Sunscreen Sunscreen	
USES: *Helps prevent with other sun protect decreases the risk of sl caused by the sun.	tion measur	res (see directions),	
WARNINGS: *For exter damaged or broken skir out of eyes, Rinse with consult physician if irrita of reach of children. If p attention or contact pois	 *When usin water to ren tion or rash roduct is swa 	ng this product keep nove. *Stop use and develops. *Keep out allowed, get medical	
DIRECTIONS: *Apply liberally 15-min *Reapply: -At least ever -Immediately after swim SUN PROTECTION MEA To decrease this risk, broad spectrum protec higher, along with or including: -Limit time in the sun, es -Viveral rong seeve shirt	y two-hours ming, sweati SURES: Speni cancer and e regularly u tion and an ther sun pr becially betw	s. ing or towel drying, ding time in the sun early skin aging, use sunscreen with SPF rating of 15 or rotection measures ween 10am and 2pm.	
-For children under 6-m			4
OTHER INGREDIENTS: Aloe Barbadensis Leaf (Deionized Water), Ce Nucifera (Coconut) C Stearate, Helianthus Ar Stearate, Phenox Styrene/Acrylates Cop (Vitamin E), Zemea (Corr	tyl Alcohol, bil, Ethylhex nnuus (Sunfi yethanol, iolymer, To	Citric Acid, Cocos cylglycerin, Glyceryl lower) Oil, PEG-100 Polysorbate-80, pcopheryl Acetate	
OTHER INFORMATION *Protect this product t sunlight.		ive heat and direct	
Made by: Pure Source, LLC: 9750 NW 17th St. N Information: 1 (866) 565-5750. Manufactured for: Alfa Importação de Medica conjunto 05 lote 10/11	Aiami, Florid Hosting Dis mentos e A l i	la 33172 Contact tribuição e imentos Eire li. ADE	-
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PROTETOR SOLAR GRIP ACTION FPS 40

octinoxate, octisalate, octocrylene, avobenzone cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:72872-137	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
0	ety gredient Name		Basis of Stre	ength	Strength
0	gredient Name	51)	Basis of Stre OCTINOXATE	U	Strength 75 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

Ingredient Name ZY81Z83H0X) OR) 936JST6JCN) PRATE (UNII: 2968PHW8QP) L0073W7L) V(UNII: 147D247K3P)		Strength
0R) 936JST6JCN) PRATE (UNII: 2968PHW8QP) L0O73W7L)		
936JST6JCN) RATE (UNII: 2968PHW8QP) L0O73W7L)		
PRATE (UNII: 2968PHW8QP) L0073W7L)		
L0O73W7L)		
N (UNII: 147D247K3P)		
RATE (UNII: 230 O U9 XXE4)		
LOWERING TOP (UNII: BKJ0J3D1BP)		
II: YD0 1N1999R)		
III: HIE492ZZ3T)		
l: 6 O Z P 3 9 Z G 8 H)		
(UNII: H4N855PNZ1)		
))		
Package Description	Marketing Start Date	Marketing End Date
mL in 1 TUBE; Type 0: Not a Combination Product	05/10/2019	
mation		
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
part352	05/10/2019	
	II: YD0 1N1999R) III: HIE492ZZ3T) : 6 OZP39ZG8H) (UNII: H4N855PNZ1))) Package Description mL in 1 TUBE; Type 0: Not a Combination Product mation Application Number or Monograph Citation	II: YD0 1N1999R) III: HIE492ZZ3T) : 6 OZP39ZG8H) (UNII: H4N855PNZ1)) Package Description Marketing Start Date mL in 1 TUBE; Type 0: Not a Combination Product 05/10/2019 Marketing Start Date mation Application Number or Monograph Citation Marketing Start Date

Labeler - Alfa Distribution and Imports (944443265)

Revised: 5/2019

Alfa Distribution and Imports