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.

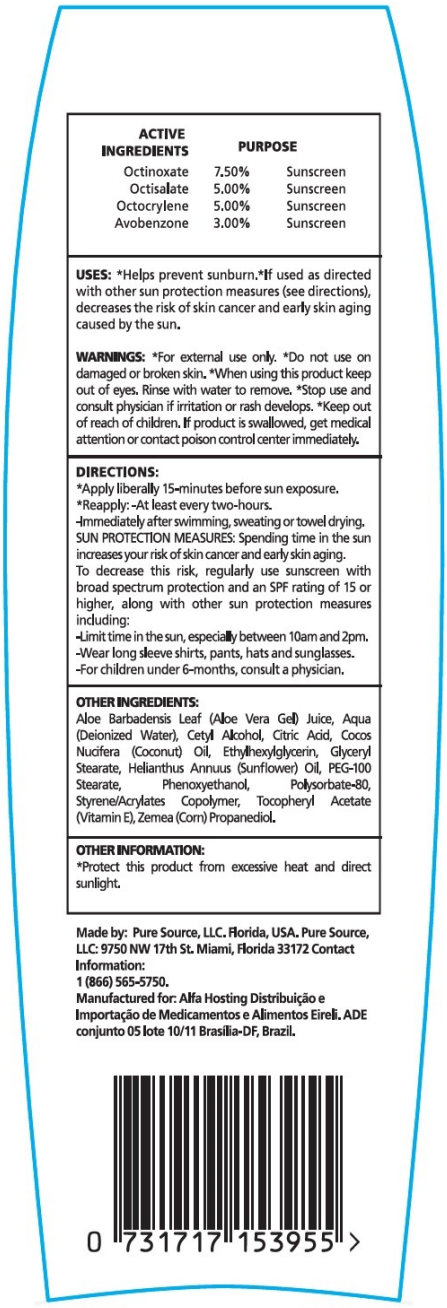
OTHER INGREDIENTS:

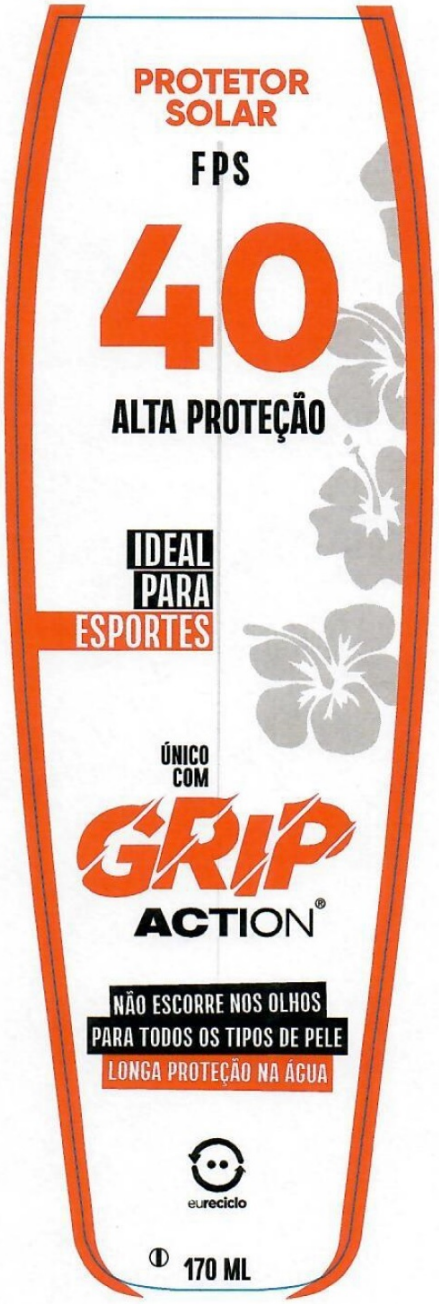
Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Cetyl Alcohol, Citric Acid, Cocos Nucifera (Coconut) Oil, Ethylhexylglycerin, Glyceryl Stearate, Helianthus Annuus (Sunflower) Oil, PEG-100 Stearate, Phenoxyethanol, Polysorbate-80, Styrene/Acrylates Copolymer, Tocopheryl Acetate (Vitamin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

OTHER INFORMATION:

*Protect this product from excessive heat and direct sunlight.

Package Labeling:





PROTETOR SOLAR GRIP ACTION FPS 40

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72872-137
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CORN (UNII: 0N8672707O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72872-137-17	170 mL in 1 TUBE; Type 0: Not a Combination Product	05/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/10/2019	

Labeler - Alfa Distribution and Imports (944443265)

Revised: 5/2019 Alfa Distribution and Imports