

**OCTINOXATE,OCTISALATE,AVOBENZONE,OCTOCRYLENE,ENSULIZOLE,TITANIUM DIOXIDE- octinoxate,octisalate,avobenzene,octocrylene,ensulizole,titanium dioxide cream
PROKPIL SAS**

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.

LOSANIKA COFFEE BB CREAM BROAD SPECTRUM SPF 30 - Avobenzene 2%,Octocrylene 2%,Octinoxate 6%,Ensulizole 2%,Octisalate 4.5%. Titanium Dioxide 2.4% CREAM

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PURPOSE:

Sunscreen

DRUG FACTS:

Active Ingredients:

AVOBENZONE 2%

OCTOCRYLENE 2%

OCTINOXATE 6%

ENSULIZOLE 2%

OCTISALATE 4.5%

TITANIUM DIOXIDE 2.4%

USES:

For all sunscreen drug products:
"helps prevent sunburn

WARNING:

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 or irritation develops or lasts.

Keep out of reach of children:

If the product is swallowed get medical help or contact a poison control center right away.

Directions:

Apply generously and evenly 15 minutes before sun exposure

Reapply at least every two hours

Use water resistant sun protector if swimming or sweating.

Sun protection measures:

Overexposure to the sun is dangerous. Increases the risk of causing skin cancer and premature aging.

To reduce the risk, regularly use sunscreen with broad spectrum SPF 15 or higher, combined with other sun protection measures.

Limit exposure time especially between 10 am - 2 pm.

Wear long sleeves, hat and glasses.

Children under 6 months of age ask a doctor.

Inactive Ingredients:

Water/Aqua, Aloe Barbadensis Leaf Water, Coffea Arabica Seed Extract, Coffea Arabica Seed Oil, Ethylhexyl Methoxycinnamate, Ethylhexyl Salicylate, C12-15 Alkyl Benzoate, Aluminum Starch Octenylsuccinate, Butyl Methoxydibenzoylmethane, Phenylbenzimidazole Sulfonic Acid, Octocrylene, Propylheptyl Caprylate, Titanium Dioxide, Calendula officinalis flower extract, Cetearyl Alcohol, Dicaprylyl Carbonate (and) Stearalkonium Hectorite (and) Propylene Carbonate, Polyglyceryl-2 Dipolyhydroxystearate, Sodium Stearoyl Glutamate, Tocopheryl Acetate, Panthenol, Sodium Polyacrylate, Phenoxyethanol and Caprylyl Glycol, Xanthan Gum, Polyamide - 3, Cymbopogon citratus leaf oil, Lippia Alba Leaf/Stem Oil, Citrus nobilis (mandarin orange) peel oil, CI 77891 (Titanium dioxide), CI 77491 (Iron oxide red), CI 77492 (Iron oxide yellow), CI 77499 (Iron oxide Black).

Other Information:

Protect from excessive heat and direct sunlight.

Formulated with out:

Parabens, silicones, mineral oils, paraffins and synthetic fragrances

CONTENT OF LABELING



OCTINOXATE,OCTISALATE,AVOBENZONE,OCTOCRYLENE,ENSULIZOLE,TITANIUM DIOXIDE

octinoxate,octisalate,avobenzene,octocrylene,ensulizole,titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71801-541
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	2 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
GLYCERIN (UNII: PDC6A3COOX)	

POLYAMIDE-3 (12000 MW) (UNII: L7P3YWF22X)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
WEST INDIAN LEMONGRASS OIL (UNII: 5BIA40E9ED)	
LIPPIA ALBA WHOLE (UNII: 76HT054LK1)	
MANDARIN OIL (UNII: NJO720F72R)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
ARABICA COFFEE OIL (UNII: IK55HKE887)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
PROPYLHEPTYL CAPRYLATE (UNII: 991Z19V2OD)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PANTHENOL (UNII: WW9CM0O67Z)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71801-541-01	30 g in 1 BOX; Type 0: Not a Combination Product	09/01/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2017	

Labeler - PROKPIL SAS (886026583)

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