

**OCTISALATE, OCTOCRYLENE, OCTINOXATE, ZINC OXIDE, TITANIUM DIOXIDE, ENSULIZOLE- octisalate, octocrylene, octinoxate, zinc oxide, titanium dioxide, ensulizole 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.*

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**ALOE & CALENDUAL ANTIOXIDENT SUNSCREEN BROAD SPECTRUM SPF30**

**LOSANIKA ALOE & CALENDULA ANTIOXIDANT SUNSCREEN BROAD SPECTRUM SPF 30 - ENSULIZOLE 2.0 %, TITANIUM DIOXIDE 2.4 %, OCTOCRYLENE 3.0 %, ZINC OXIDE 3.5 %, OCTISALATE 4.5 %, OCTINOXATE 6.5 %**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they maybe marketed if they comply with regulations and policies. FDA has not evaluated weather this product complies.

**PURPOSE:**

SUNSCREEN

**DRUG FACTS:**

**ACTIVE INGREDIENTS:**

ENSULIZOLE 2.0 %

TITANIUM DIOXIDE 2.4 %

OCTOCRYLENE 3.0 %

ZINC OXIDE 3.5 %

OCTISALATE 4.5 %

OCTINOXATE 6.5 %

**USES:**

- Helps prevent sunburn
- If used as directed with other sun protection measures (seek Directions), decreases the risk of skin cancer and early skin aging caused by the sun.

**WARNING:**

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 or irritation develops or lasts.

**KEEP OUT OF REACH OF CHILDREN:**

If swallowed, get medical help or contact a Poison Control Center right away

**DIRECTIONS:**

Apply liberally 15 minutes before sun exposure

Use water resistant sun protector if swimming or sweating.

Reapply at least every two hours.

Children under six months: ask a doctor

**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.

**INACTIVE INGREDIENTS:**

Water (Aqua), Aloe vera (Aloe) Leaf juice, Calendula officinalis (calendula) flower extract, Aluminum Starch Octenylsuccinate, C12-15 Alkyl Benzoate, Propylheptyl Caprylate, Dicaprylyl Carbonate (and) Stearalkonium Hectorite (and) Propylene Carbonate, Cetearyl Alcohol, Hydrogenated Castor Oil, Polyglyceryl-2 Dipolyhydroxystearate, Coffea arabica (Coffee) seed oil, Sodium Stearoyl Glutamate, Tocopheryl Acetate(E), Niacinamide (B3), Panthenol, Glycerin, Xanthan Gum, Fragrance, Phenoxyethanol (And) Decylene Glycol (And) Caprylyl Glycol, Bixa Orellana Seed Extract (Annato), Cymbopogon citratus (lemongrass) oil, Zingiber officinale (ginger) root oil, Citrus sinensis (sweet orange) peel oil, Lippia alba (bushy matgrass) leaf/stem oil.

**OTHER INFORMATION:**

Protect from excessive heat and direct sunlight.

Formulated without: parabens, silicones, mineral oils, synthetic dyes.

**CONTENT OF LABELING:**

LOSANIKA  
NATURAL BIOCOSMETICS

LOSANIKA®  
NATURAL BIOCOSMETICS

Aloe & Calendula  
**Antioxidant**  
**Sunscreen**  
**Pantalla Solar**  
With Niacinamide & Ginger

**SPF 30**

Broad spectrum  
UVA-UVB  
Ámplio Espectro  
UVA-UVB



Anti-Aging / restore the  
protective skin barrier

Anti-edad / Ayuda a proteger  
del daño cutáneo producido  
por el sol

Citrus Honey

Net Wt.  
2.1 Oz/60g

Bio protector sunscreen with rejuvenating and antioxidant effect. Its innovative formula combines science and nature evaluated under international parameters with adequate protection of broad spectrum against UVB / UVA rays. Contains mineral and organic sunscreen filters linked with botanical extracts, antioxidants, vitamins and natural emollients that help combat oxidative stress, premature aging, skin damage and helps prevent sunburn. Its delicate formula with active anti-pollution detox helps protect the protective barrier of the skin, it quickly absorbs giving an illuminating finish. Ideal for aesthetic treatments.

BioProtector solar con efecto rejuvenecedor y antioxidante. Su innovadora formula combina la ciencia y la naturaleza evaluado bajo parámetros internacionales que garantizan una adecuada protección de amplio espectro contra las radiaciones UVB/UVA, visible e infrarroja. Contiene pantallas minerales, filtros solares orgánicos unidos a Fito extractos botánicos, vitaminas antioxidantes y emolientes naturales que combaten el stress oxidativo, envejecimiento prematuro, daño cutáneo y Previene las quemaduras solares. Delicada formula con activos detox anti contaminación ayudan a restaurar la barrera protectora de la piel, es de rápida absorción dando un acabado iluminador ideal para tratamientos estéticos.

MANUFACTURED / FABRICADO Cali,  
Colombia by Prokpil SAS for  
Losanika S.A.S

NUMERO DE NOTIFICACIÓN:  
NSOC 85549-18CO

QUESTIONS / PREGUNTAS

Tel:(57)(2) 3375707 or info@losanika.com  
www.losanika.com

**Drug Facts**

Active Ingredient	Purpose
Ethylhexyl Methoxycinnamate 6.5%	(Sunscreen UVA)
Ethylhexyl Salicylate 4.5%	(Sunscreen UVB)
Zinc oxide 3.5%	(Sunscreen UVA-UVB)
Octocrylene 3.0%	(Sunscreen UVA-UVB)
Titanium Dioxide 2.4%	(Sunscreen UVA-UVB)
Phenylbenzimidazole Sulfonic Acid 2.0 %	(Sunscreen UVA-UVB)

**Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (seek **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  
**Stop use and ask doctor** if rash occurs  
**When using this product** keep out of eyes.  
**Rinse with water to remove**  
**Keep out of reach of children.**  
If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally 15 minutes before sun exposure
- Use water resistant sun protector if swimming or sweating.
- Reapply at least every two hours.
- Children under six months: ask a doctor

**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.

**Drug facts**

**Inactive Ingredients**

Water (Aqua), Aloe vera (Aloe) Leaf Juice, Calendula officinalis (calendula) flower extract, Aluminum Starch Octylsuccinate, C12-15 Alkyl Benzoate, Propylheptyl Caprylate, Dicaprylyl Carbonate (and) Stearalkonium Hectorite (and) Propylene Carbonate, Cetearyl Alcohol, Hydrogenated Castor Oil, Polyglyceryl-2 Dipolyhydroxystearate, Coffea arabica (Coffee) seed oil, Sodium Stearoyl Glutamate, Tocopheryl Acetate(E), Niacinamide (B3), Panthenol, Glycerin, Xanthan Gum, Fragrance, Phenoxymethylol (and) Decylene Glycol (and) Caprylyl Glycol, Bixa Orellana Seed Extract (Annatto), Cymbopogon citratus (lemongrass) oil, Zingiber officinale (ginger) root oil, Citrus sinensis (sweet orange) peel oil, Lippia alba (bushy matgrass) leaf/stem oil.  
**Other information / Información:**  
Protect from excessive heat and direct sunlight  
Formulated **without:** parabens, silicones, mineral oils, synthetic dyes

**Indicaciones de uso:**  
Aplicuela, generosa y uniformemente, 15 minutos antes de la exposición a la radiación solar. Reaplique por lo menos cada dos horas. Use protector solar resistente al agua si nada o sudó. Se recomienda aplicar al final de tratamientos estéticos.

**Este filtro solar es potenciado con antioxidantes.**

**Precauciones:**

Solo para uso externo. Suspéndalo su uso y pregunte al doctor si presenta irritaciones.

Evite el contacto con los ojos. Use agua para removerlo. Manténgalo fuera del alcance de los niños. Si el producto es ingerido consulte al médico. No usar en menores de 6 meses.

**Medidas de protección solar:**

La sobre exposición al sol es peligrosa para la salud e incrementa el envejecimiento prematuro. Para disminuir el riesgo, use regularmente protector solar de amplio espectro con SPF15 o mayor, combinadas con otras medidas de protección solar. Limite el tiempo de exposición especialmente entre 10 am a 2 pm. Use camisas de manga larga, gorro y gafas.

SPF	SPF	SPF	SPF
BAJO 6-10	MEDIO 15-20-25	ALTO 30-50	MUY ALTO 60+

LOT:  
EXP:



**OCTISALATE, OCTOCRYLENE, OCTINOXATE, ZINC OXIDE, TITANIUM**

# DIOXIDE,ENSULIZOLE

octisalate,octocrylene,octinoxate,zinc oxide,titanium dioxide,ensulizole cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71801-542
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.4 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
<b>ENSULIZOLE</b> (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	2 g in 100 g
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.5 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.5 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3.5 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>PROPYLHEPTYL CAPRYLATE</b> (UNII: 991Z19V2OD)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE</b> (UNII: 9229XJ4V12)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BIXA ORELLANA SEED</b> (UNII: O87354RZ5A)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>WEST INDIAN LEMONGRASS OIL</b> (UNII: 5BIA40E9ED)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DECYLENE GLYCOL</b> (UNII: S57M60MI88)	
<b>GINGER OIL</b> (UNII: SAS9Z1SVUK)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>STEARALKONIUM HECTORITE</b> (UNII: OLY698AH5P)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)	
<b>ARABICA COFFEE OIL</b> (UNII: IK55HKE887)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>LIPPIA ALBA WHOLE</b> (UNII: 76HT054LK1)	
<b>ORANGE OIL</b> (UNII: AKN3KSD11B)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71801-542-01	30 g in 1 BOX; Type 0: Not a Combination Product	06/18/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/18/2018	

**Labeler** - PROKPIL SAS (886026583)

Revised: 3/2021

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