

## **ALOEVELLA - titanium dioxide, zinc oxide cream**

**Ojas Enterprises LLC**

*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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### **Drug Facts**

#### **Active ingredients**

Titanium dioxide 5%

Zinc Oxide 15%

#### **purpose**

Sunscreen

#### **Uses**

- Helps prevent sunburn

#### **Warnings:**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increase your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging

#### **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 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- children under 6 months: Ask a doctor

#### **Inactive ingredients**

water, Almond oil, Sesame oil, Soy bean oil, Jojoba oil, Cetearyl olivate, sorbitan olivate, Stearic acid, Aloevera, Vitamin E oil, Sodium Benzoate, Cetyl Alcohol, Whetgerm oil, D Panthanol, Olive leaf extract,

fragrance, Carrot extract, Green tea extract, Licorice extract, Neem extract, Cucumber extract, Glyceryl stearate, Xanthan gum

#### **Other information**

- protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free 1-866-855-9006

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<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide 5% Zinc Oxide 15%	Sunscreen
<b>Uses :</b> Help prevent sunburn	
<b>Warnings</b>	
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<b>Directions</b>	
<ul style="list-style-type: none"> <li>• Apply liberally 15 minutes before sun exposure</li> <li>• Reapply:               <ul style="list-style-type: none"> <li>• After 40 minutes of swimming or sweating</li> <li>• Immediately after towel drying</li> <li>• At least every 2 hours</li> </ul> </li> <li>• Children under 6 month: Ask a doctor</li> </ul>	
<b>Inactive ingredients</b>	
Water, Almond Oil, Sesame Oil, Soy Bean Oil, Jojoba Oil, Cetearyl Oliviate, Sorbitan Oliviate, Stearic Acid, Aloe vera, Vitamin E Oil, Sodium Benzoate, Cetyl Alcohol, Whetgarm Oil, D Panthanol, Olive Leaf Extract, Fragrance, Carrot Extract, Green Tea Extract, Licorice Extract, Neem Extract, Cucumber Extract, Glyceryl Stearate, Xantham Gum	
<b>Other information</b>	
• Protect this product from excessive heat and direct sun	
<b>Questions or comments?</b>	
Call toll free 1-866-855-9006	

**DISTRIBUTED BY :** © OJAS Enterprise LLC,  
87 Taft Avenue, Newburgh,  
New York 12550

**Batch No. :**

**Mfg. Date :**

**Exp. Date :**

Made in India

**No synthetic preservatives , paraben-free,  
No SLS, Hypo-allergenic, and PH balanced.  
Not tested on animals.**

 Visit our website [www.aloevella.com](http://www.aloevella.com) 



**aloevella**  
BE NATURAL

moisturizing  
**SUNSCREEN**

**SPF 30**

for all skin types  
**ALL NATURAL**  
contains over 90% organic  
**ALOE VERA**

**WATER RESISTANT  
(40 MINUTES)**

Nt. Wt. 7.05 oz. / 200 grams

**ALOEVELLA**

titanium dioxide, zinc oxide cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:55115-2041

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
SESAME OIL (UNII: QX10HYY4QV)	
SOYBEAN OIL (UNII: 241ATL177A)	
JOJOBA OIL (UNII: 724GKU717M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WHEAT GERM OIL (UNII: 14C97E680P)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
CARROT (UNII: L56Z1JK48B)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
LICORICE (UNII: 61ZBX54883)	
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)	
CUCUMBER (UNII: YY7C30VXJT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55115-2041-1	200 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/14/2011	

**Labeler** - Ojas Enterprises LLC (968626502)**Establishment**

Name	Address	ID/FEI	Business Operations
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Illban Remedies Private Limited		9 15784131	manufacture
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Revised: 12/2011

Ojas Enterprises LLC