# PANOXYL OIL CONTROL MOISTURIZER- titanium dioxide and zinc oxide lotion Crown Laboratories

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.

-----

### PanOxyl Oil Control Moisturizer with SPF 30 Mineral Sunscreen

### **Active Ingredients**

Titanium Dioxide - 1.0% Zinc Oxide - 7.8%

### **Purpose**

Sunscreen

#### Uses

- Helps prevent sunburn and photodamage caused by UVA/UVB exposure
- Higher SPF gives more sunburn protection
- If used as directed with other sun protection measures (see Directions), decreases the risks of skin cancer and early skin aging caused by the sun

### Warnings

- When using this product Keep out of eyes. Rinse with water to remove
- Stop use and ask doctor if rash or irritation occurs
- Do not use: On damaged or broken skin If allergic to any ingredient
- If swallowed, get medical help or contact a Poison Control Center

#### **Directions**

- Shake well prior to use
- Apply liberally to dry skin 15 minutes before sun exposure
- For topical use only
- Keep out of reach of children Children under 6 months: ask a doctor
- **Sun Protection Measures**: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
- Limit time in the sun, especially from 10 a.m. 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

• **Reapply to dry skin**: • At least every 2 hours • Use a water resistant suscreen if swimming for sweating

#### Other Information

- Protect the product in this container from excessive heat and direct sun
- May stain some fabrics

### **Inactive Ingredients**

Alumina, Aluminum Starch Octenylsucciante, Aluminum Stearate, Beeswax, C12-15 Alkyl Benzoate, C13-14 Isoparaffin, Caffeine, Camellia Sinensis Leaf (Green Tea) Extract, Caprylyl Glycol, Chlorphenesin, Cyclomethicone, Dimethoxydiphenylsilane/Triethoxycaprylylsilane Crosspolymer, Isostearyl Alcohol, Laureth-7, Lauryl PEG/PPG 18/18 Methicone, Phenoxyethanol, Polyacrylamide, Polyhydroxystearic Acid, Purified Water, Sodium Hyaluronate, Triethoxycaprylylsilane

#### **Questions?**

Call **800.877.8869** 

or visit www.panoxyl.com

Crown Laboratories, Inc., Johnson City, TN 37604

Made in USA

### PanOxyl Oil Control Moisturizer 1.7oz Tube

DERMATOLOGIST RECOMMENDED

PanOxyl AM

OIL CONTROL MOISTURIZER

Broad Spectrum SPF 30

Mineral Sunscreen

Lightweight Daily Moisturizer

Absorbs Excess Oil

**UVA/UVB Protection** 

Won't Clog Pores

P11833.00



# **Drug Facts**

### Active Ingredients

Titanium Dioxide 1.0% Zinc Oxide 7.8% Purpose Sunscreen Sunscreen

Uses Helps prevent sunburn and photodamage caused by UVA/UVB exposure • Higher SPF gives more sunburn protection
 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

When using this product • Keep out of eyes. Rinse with water to remove • Stop use and ask a doctor if rash or irritation occurs **Do not use:** • On damaged or broken skin • If allergic to any ingredient • If swallowed, get medical help or contact a Poison Control Center

Directions Shake well prior to use • Apply liberally to dry skin 15 minutes before sun exposure • For topical use only • Keep out of reach of children • Children under 6 months: ask a doctor • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially from 10 a.m.−2 p.m. • Wear long-sleeved shirts, pants, hats, and sunglasses Reapply to dry skin: • At least every 2 hours • Use a water resistant sunscreen if swimming or sweating

**Other Information** Protect the product in this container from excessive heat and direct sun • May stain some fabrics

Inactive Ingredients Alumina, Aluminum Starch
Octenylsuccinate, Aluminum Stearate, Beeswax, C12-15 Alkyl
Benzoate, C13-14 Isoparaffin, Caffeine, Camellia Sinensis Leaf
(Green Tea) Extract, Caprylyl Glycol, Chlorphenesin,
Cyclomethicone, Dimethoxydiphenylsilane/Triethoxycaprylylsilane
Crosspolymer, Isostearyl Alcohol, Laureth-7, Lauryl PEG/PPG 18/18
Methicone, Phenoxyethanol, Polyacrylamide, Polyhydroxystearic
Acid, Purified Water, Sodium Hyaluronate, Triethoxycaprylylsilane

Questions or Comments? Call 800-877-8869 or visit www.panoxyl.com.

Crown Laboratories, Inc. Johnson City, TN 37604 Made in USA



### PanOxyl Oil Control Moisturizer 1.7oz Carton

New

DERMATOLOGIST RECOMMENDED

PanOxyl AM

OIL CONTROL MOISTURIZER

**Broad Spectrum SPF 30** 

Mineral Sunscreen

Lightweight Daily Moisturizer
Absorbs Excess Oil
UVA/UVB Protection
Won't Clog Pores
P11834.01



### PANOXYL OIL CONTROL MOISTURIZER

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0316-0263
Route of Administration	TOPICAL		

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	83.4 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CAFFEINE (UNII: 3G6A5W338E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: 1670DAL4SZ)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ISOSTEARYL ALCOHOL (UNII: Q6130CQ44Y)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRW)	
DIMETHOXYDIPHENYLSILANE (UNII: 02QB6788GC)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:0316-0263- 02	1 in 1 CARTON	03/09/2021		
1	48 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/09/2021	

# **Labeler -** Crown Laboratories (079035945)

## **Establishment**

Name	Address	ID/FEI	Business Operations
Crown Laboratories		079035945	manufacture(0316-0263)

Revised: 2/2023 Crown Laboratories