# MONGDIES EXCELLENT SUN- zinc oxide cream 360Perspective Inc.

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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#### **ACTIVE INGREDIENT**

Zinc Oxide 20.02%

### **PURPOSE**

Sunscreen

#### WARNINGS

For external use only. If skin irritation occurs or increases, discontinue use and consult a physician. Keep out of reach of children.

#### **KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children.

### Uses

An inorganic sun cream with no irritation that contains plant extracts to provide moisturizing and soothing effects.

#### **Directions**

Evenly apply to areas when sun protection is required.

## Other Information

Avoid direct sunlight.

#### **INACTIVE INGREDIENTS**

Water, Coco-Caprylate/Caprate, Propanediol, Glycerin, Pentylene Glycol, Polyhydroxystearic Acid, Prunus Amygdalus Amara (Bitter Almond) Kernel Oil, Camellia Sinensis Leaf Extract, Pyrus Malus (Apple) Leaf Extract, Jasminum Officinale (Jasmine) Flower Water, Vanilla Planifolia Fruit Extract, Water, Anthemis Nobilis Flower Extract, Eucalyptus Globulus Leaf Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, Origanum Majorana Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf

Extract, Salvia Officinalis (Sage) Leaf Extract, Origanum Vulgare Leaf Extract, Beheneth-25, Methyl Methacrylate Crosspolymer, Silica, Triethoxycaprylylsilane, Cetearyl Olivate, Sorbitan Olivate, Ammonium Acryloyldimethyltaurate/VP Copolymer, Glyceryl Stearate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Caprylyl Glycol, Polyacrylate Crosspolymer-6, Trisodium Ethylenediamine Disuccinate, Madecassoside, Asiaticoside, Asiatic Acid, Madecassic Acid, Butylene Glycol, 1,2-Hexanediol, Xanthan Gum

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



zinc oxide cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70477-030

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength

Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) ZINC CATION 12.01 g in 60 mL

# **Inactive Ingredients**

inactive ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
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Pentylene Glycol (UNII: 50C1307PZG)

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70477-030- 02	1 in 1 CARTON	09/01/2021	
1	NDC:70477-030- 01	60 mL in 1 TUBE; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing	larketing Application Number or Monograph Marketing Start Marketing End			
Category	Citation	Date	Date	
OTC monograph not final	part352	09/01/2021		

# Labeler - 360Perspective Inc. (689606142)

# Registrant - 360Perspective Inc. (689606142)

# **Establishment**

Name	Address	ID/FEI	Business Operations		
Cosmax, Inc.		689049693	manufacture(70477-030)		

Revised: 9/2021 360Perspective Inc.