

**CREAM- octinoxate, zinc oxide cream**  
**Oxygen Development 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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**Westmore Beauty 10-in-1 coverage perfecter CC cream Broad spectrum spf 25 sunscreen - Fair**

**active ingredients**

Octinoxate 5%, Zinc Oxide 5%. Purpose: sunscreen

**purpose**

sunscreen

**uses**

- helps prevent sunburn
- If used as directed with other sun protection measure (see directions), decreases the risk of skin cancer and early skin aging caused by sun

**warnings**

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 swallowed, get medical help or contact a poison control center right away

**directions**

- Apply liberally 15 mins before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- 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 of at least 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10am - 2pm
- wear long-sleeved shirts, pants, hats, and sunglasses

### **inactive ingredients**

water (aqua/eau), Acetamidoethoxyethanol, Tridecyl Trimellitate, Octyldodecyl Neopentanoate, polysilicone-31, niacinimide, Cyclopentasiloxane, Cetyl Alcohol, C12-15 Alkyl Benzoate, Butylene Glycol, Aluminum Starch Octenylsuccinate, Caprylyl Methicone, Sodium Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Phenoxyethanol, Isohexadecane, mica, Potassium Cetyl Phosphate, Peg-8 Dimethicone, PEG-100 Stearate, Glyceryl Stearate, glycerin, yeast extract, xanthan gum, Polyhydroxystearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, Triethoxycaprylylsilane, polysorbate 80, soy amino acids, Ethylhexylglycerin, Tetrahexyldecyl Ascorbate, Arnica Montana Flower Extract.

### **other information**

protect this product from excessive heat and direct sun

### **package label - primary**



PANTONE  
5255C

TUBE  
COLOR

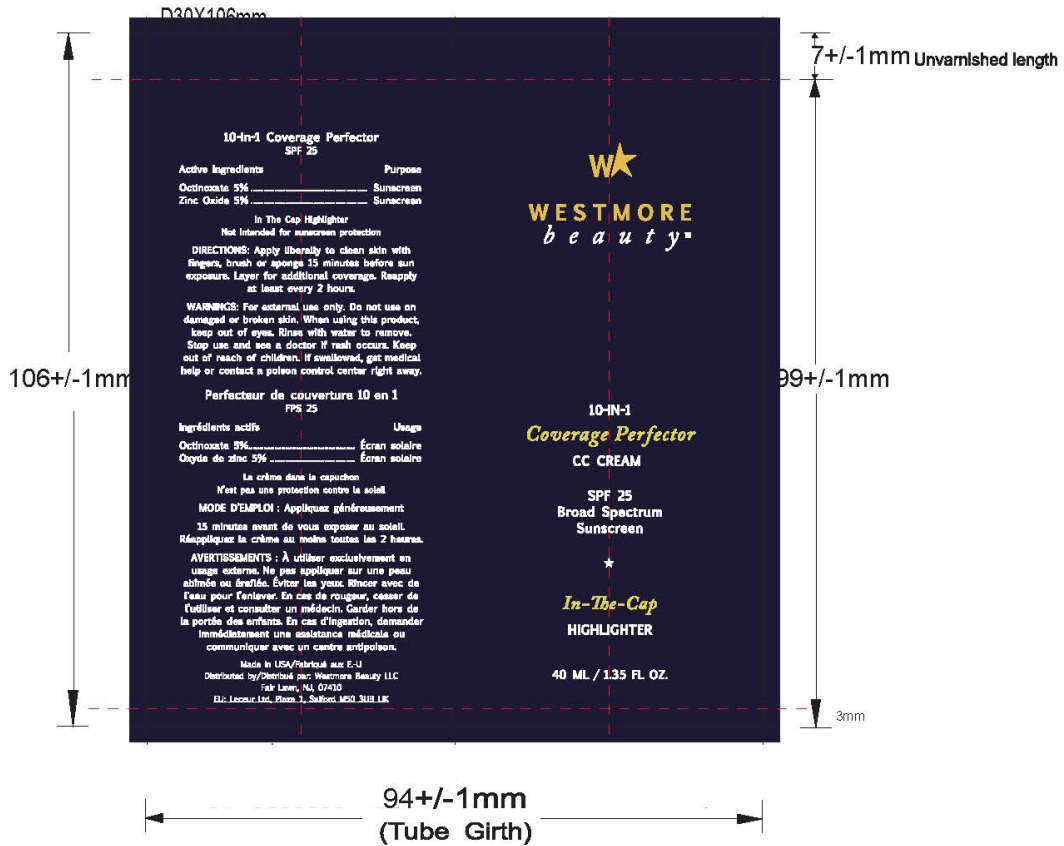


White



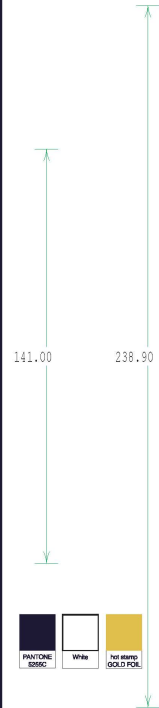
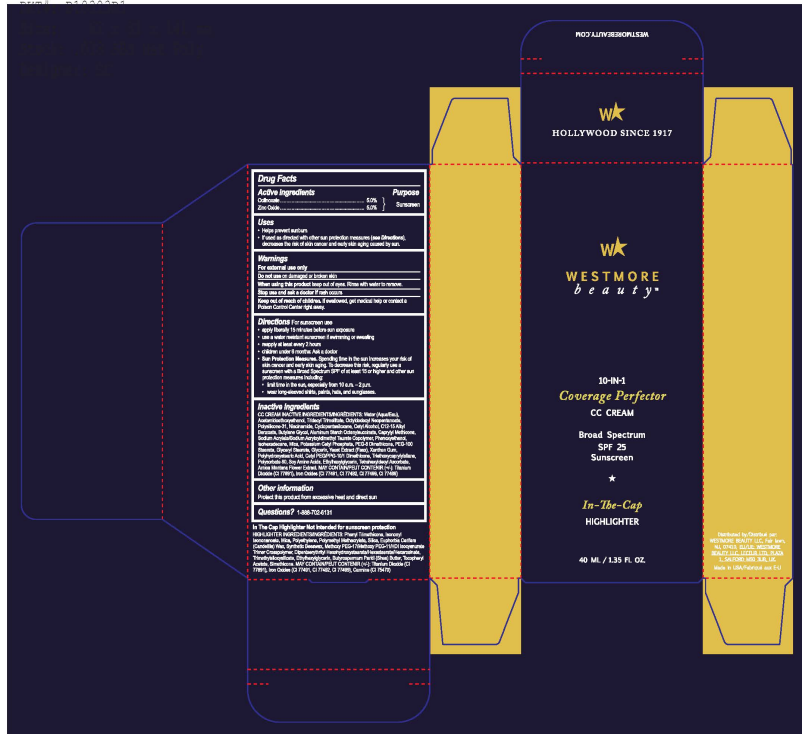
hot stamp  
GOLD FOIL

DECO CALL OUTS



package label - secondary

Date: August 31, 2017  
 Cust: Westmore  
 Desc: 10 in 1 Tinted Moisturizer



## CREAM

octinoxate, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61354-070
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mg in 100 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 mg in 100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW)</b> (UNII: 1DXE3F3OZX)	

ISOHEXADECANE (UNII: 918X1OUF1E)
PEG-8 DIMETHICONE (UNII: GIA7T764OD)
WATER (UNII: 059QF0KO0R)
PEG-100 STEARATE (UNII: YD01N1999R)
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
NIACINAMIDE (UNII: 25X51I8RD4)
GLYCERIN (UNII: PDC6A3C0OX)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ACETAMIDOETHOXYETHANOL (UNII: LVX2APC4XR)
POLYSILICONE-15 (UNII: F8DRP5BB29)
CETYL ALCOHOL (UNII: 936JST6JCN)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-070-07	1 in 1 CARTON	02/22/2021	02/10/2023
1	NDC:61354-070-03	40 mg 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 final	part352	02/22/2021	

**Labeler** - Oxygen Development LLC (137098492)

### Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-070)