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.

Westmore Beauty 10-in-1 coverage perfector CC cream Broad spectrum spf 25 sunscreen - Medium

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

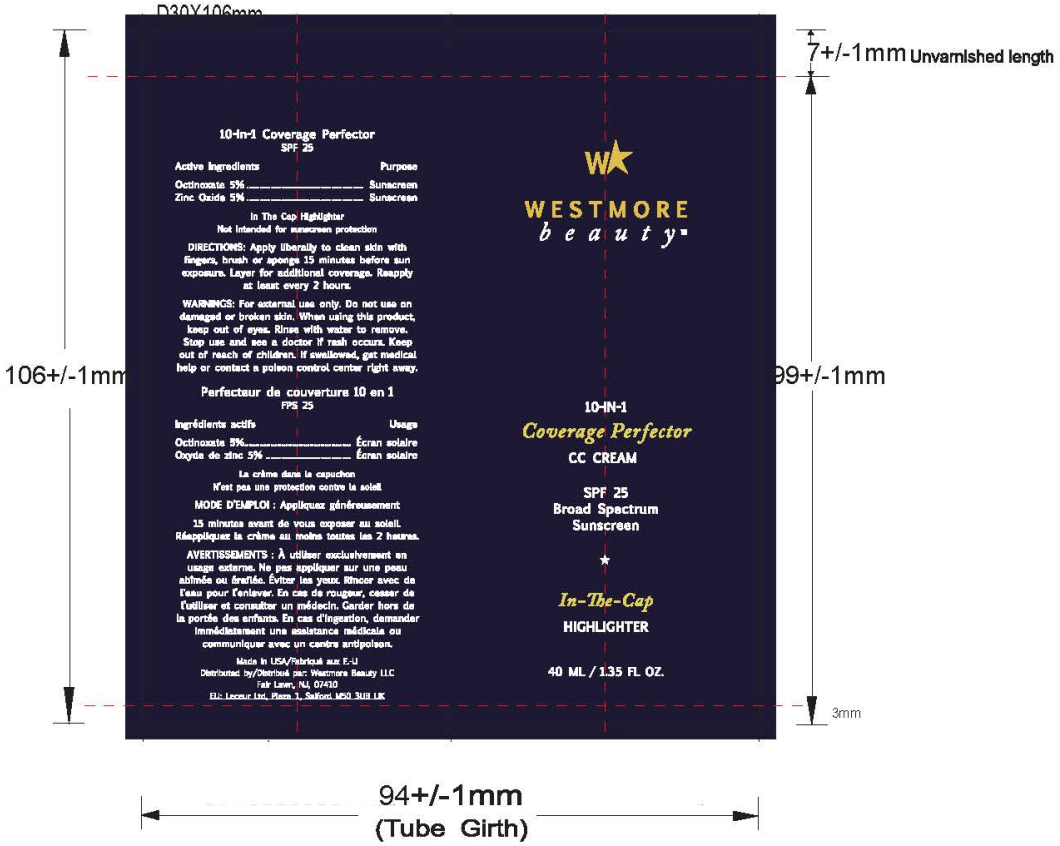
inactive ingredients

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.

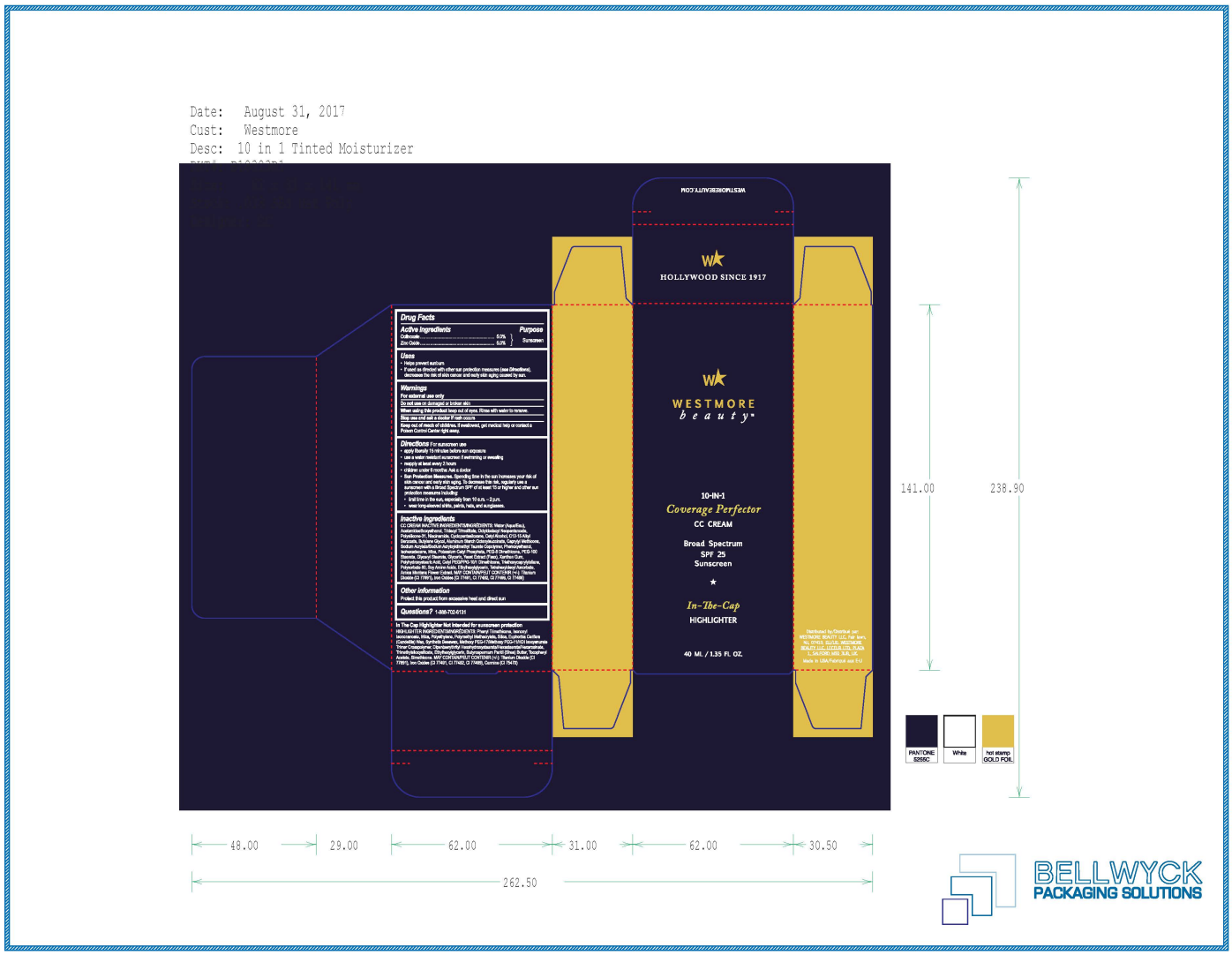
other information

protect this product from excessive heat and direct sun

package label - primary



package label - secondary



CREAM

octinoxate, zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61354-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 mg in 100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
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)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW) (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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61354-070-08	1 in 1 CARTON	02/22/2021	02/10/2023
1	NDC:61354-070-04	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)