

CYZONE EXPRESS YOUR FACE- octinoxate and oxybenzone cream
Ventura Corporation (San Juan, P.R)

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.

xpress
your face
crema facial
cy°zone

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
Octinoxate 5.5 %	sunscreen
OXYBENZONE 4.00%	sunscreen

Uses

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Provides minimal protection against sunburn

Warnings

For external use only

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally before sun exposure and as needed

Other information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

AQUA (WATER), PROPYLENE GLYCOL, CYCLOHEXASILOXANE, CYCLOPENTASILOXANE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, GLYCERYL STEARATE SE, C12-15 ALKYL BENZOATE, CETEARYL ALCOHOL, CETYL ALCOHOL, GLYCERIN, PANTHENOL, C12-14 PARETH-12, PHENOXYETHANOL, ISOPROPYL PALMITATE, GLYCERYL STEARATE, METHYL METHACRYLATE CROSSPOLYMER, DIMETHICONE, METHYL PARABEN, PROPYL PARABEN, PANAX GINSENG ROOT EXTRACT, XANTHAN GUM, CETEARETH-20, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, DIMETHICONE CROSSPOLYMER, PARFUM (FRAGRANCE), SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, DIMETHICONOL, ISOHEXADECANE, TILIA CORDATA WOOD EXTRACT, TETRASODIUM EDTA, HYDROLYZED WHEAT

PROTEIN, MANNITOL, BUTYLPARABEN, ETHYLPARABEN, TRIETHANOLAMINE, AESCULUS HIPPOCASTANUM SEED EXTRACT (AESCULUS HIPPOCASTANUM (HORSE CHESTNUT) SEED EXTRACT), POLYSORBATE 80, ISOBUTYLPARABEN, GLYCOGEN, PEG-60 ACEITE DE RICINO HIDROGENADO, FAEX EXTRACT (YEAST EXTRACT), AVENA SATIVA KERNEL EXTRACT (AVENA SATIVA (OAT) KERNEL EXTRACT), TRITICUM VULGARE GERM EXTRACT (TRITICUM VULGARE (WHEAT) GERM EXTRACT), TRITICUM VULGARE GERM OIL (TRITICUM VULGARE (WHEAT) GERM OIL), ACTINIDIA CHINENSIS FRUIT EXTRACT (ACTINIDIA CHINENSIS (KIWI) FRUIT EXTRACT), HELIANTHUS ANNUUS SEED OIL (HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL), CALCIUM PANTOTHENATE, CUCUMIS SATIVUS FRUIT EXTRACT (CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT), BIOTINUM (BIOTIN)

PRINCIPAL DISPLAY PANEL - 60 g Bottle

xpress

your *face*

crema facial

hidratante

multibeneficios

FPS 10

cy°zone

60 g e (2.1 oz.)



xpress
your face

crema facial
hidratante
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Warnings
For external use only.

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Keep out of eyes. Rinse with water.

Drug Facts (continued)

Directions
■ Apply liberally before sun exposure and as needed.

Other information
■ Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients
Aqua (water), propylene glycol, cyclohexasiloxane, cyclopentasiloxane, dimethicone/vinyl dimethicone

Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

crosspolymer, glyceryl stearate se, c12-15 alkyl benzoate, cetearyl alcohol, cetyl alcohol, glycerin, panthenol, c12-14 pareth-12, phenoxyethanol, isopropyl palmitate, glyceryl stearate, methyl methacrylate crosspolymer, dimethicone, methylparaben, propylparaben, panax ginseng root extract, xanthan gum, cetareth-20, acrylates/c10-30 alkyl

Drug Facts (continued)

acrylate crosspolymer, dimethicone crosspolymer, parfum (fragrance), sodium acrylate/ sodium acryloyldimethyl taurate copolymer, dimethiconol, isohexadecane, tilia cordata wood extract, tetrasodium edta, hydrolyzed wheat protein, mannitol, butylparaben, ethylparaben, triethanolamine, aesculus hippocastanum seed extract (aesculus hippocastanum (horse chestnut) seed extract), polysorbate 80, isobutylparaben, glycogen, peg-60 aceite de ricino hidrogenado, faex extract (yeast extract), avena sativa kernel extract (avena sativa (oat) kernel extract), triticum vulgare germ extract (triticum vulgare (wheat) germ extract), triticum vulgare germ oil (triticum vulgare (wheat) germ oil), actinidia chinensis fruit extract (actinidia chinensis (kiwi) fruit extract), helianthus annuus seed oil (helianthus annuus (sunflower) seed oil), calcium pantothenate, cucumis sativus fruit extract (cucumis sativus (cucumber) fruit extract), biotinum (biotin).

P.R.: Dist. by Ventura Corporation, Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

CYZONE EXPRESS YOUR FACE

octinoxate and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-356
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.055 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.04 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
PANTHENOL (UNII: WV9CM0O67Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
TILIA CORDATA WOOD (UNII: 674MYE89IE)	
EDETATE SODIUM (UNII: MP1J8420LU)	
MANNITOL (UNII: 3OWL53L36A)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
TROLAMINE (UNII: 9O3K93S3TK)	
HORSE CHESTNUT (UNII: 3C18L6RJAZ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
GLYCOGEN (UNII: 309GSC92U1)	
YEAST (UNII: 3NY3SM6B8U)	
OAT (UNII: Z6J799EAJK)	
WHEAT GERM (UNII: YR3G369F5A)	
WHEAT GERM OIL (UNII: 14C97E680P)	
KIWI FRUIT (UNII: 71ES77LGJC)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CALCIUM PANTOTHENATE (UNII: 568ET80C3D)	
CUCUMBER (UNII: YY7C30VXJT)	
BIOTIN (UNII: 6SO6U10H04)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-356-01	60 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	05/27/2011	

Labeler - Ventura Corporation (San Juan, P.R) (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE

Revised: 5/2011

Ventura Corporation (San Juan, P.R)