

PURIFYING OXYGENATING MOISTURIZING CREAM- mineral oil, glycerin cream
Casmara Cosmetics, SA

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.

PURIFYING OXYGENATING MOISTURIZING CREAM

DIRECTIONS

- . apply every day gently onto clean face and neck
- . can be used in the morning and/or night.

ACTIVE INGREDIENTS PURPOSE

Mineral Oil 20%.....Skin Protectant
Glycerin 6.5%..... Skin Protectant



purifying

OXYGENATING
MOISTURIZING CREAM

CRÈME OXYGÉNANTE
HYDRATANTE

SKIN PROTECTANT.
HELPS TO PREVENT DEHYDRATION
OF THE SKIN.

Pure Oxygen **01** FACIAL COLLECTION

50 ml 1.7 fl.oz.

CASMARA COSMETICS, S.A. - Cod. AMA20001TR
C/ CIUTAT DE LLIRIA, n° 29 y 31 - POL. IND. FUENTE DEL JARRO - 46988 PATERNA - (VALENCIA) SPAIN
TEL. (+34) 961 501 999 - Fabr. n° 00690CS
www.casmara.com - casmara@casmara.es - MADE IN SPAIN (EU)

Drug Facts	
Active Ingredients	Purpose
Mineral oil 17%	Skin protectant
Glycerin 6.5%	Skin protectant
Uses	
. helps to prevent dehydration of the skin.	
. helps maintain the hydrolipidic layer of the skin.	
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.	
When using this product do not get into eyes.	
Children under 6 months: ask a doctor.	
Directions	
. apply every day gently onto clean face and neck.	
. can be used in the morning and/or night.	
Other information	
. keep the product in a cool and dry place.	
Inactive Ingredients	
water, macadamia ternifolia seed oil, egg yolk extract, glyceryl stearate, phenoxyethanol, lecithin, cetyl phosphate, triethanolamine, carbomer, ribose, fragrance, sodium hyaluronate, ethylhexylglycerin, tetrasodium glutamate diacetate, BHT, tocopherol, ascorbyl palmitate.	
Questions or comments?	
- +34 961 501 999 M-F 9:00 am to 5:00 pm	



Cod. A20001V

WARNINGS

Children under 6 months: ask a doctor

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OTHER INFORMATION

keep the product in a cool and dry place.

INACTIVE INGREDIENTS

water, peg-40 castor oil, phenoxyethanol, sodium polyacrylate, betaine, cyclopentasiloxane, trideceth-6, ribose, fragrance, ethylhexylglycerin, tetrasodium glutamate diacetate, peg/ppg- 18/18 dimethicone, perfluorodecalin, simmondsia chinensis (jojoba) seed oil, ceramide np, sucrose palmitate, xanthan gum, sodium benzoate, potassium sorbate.

QUESTIONS OR COMMENTS?

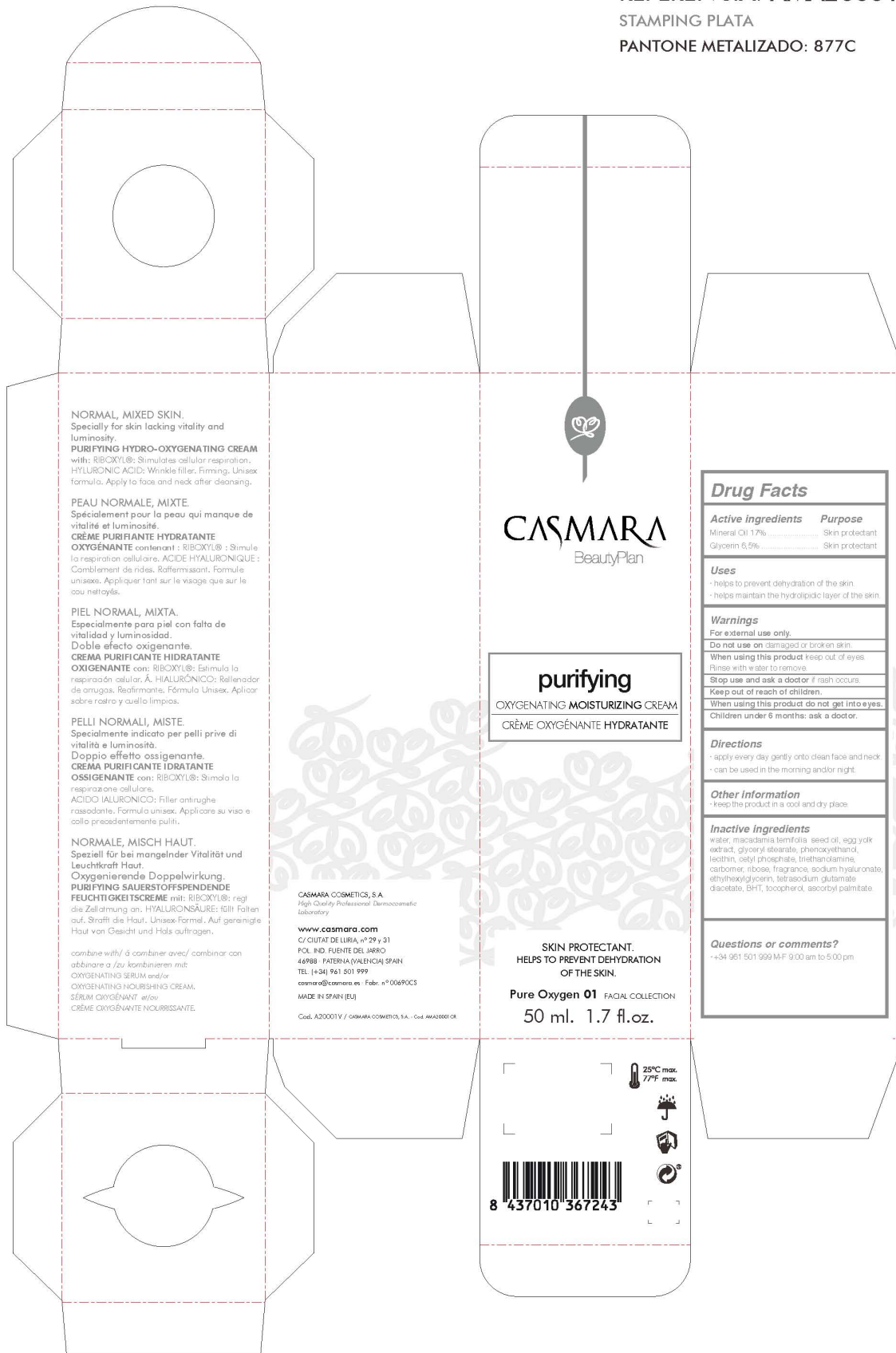
+ 34 961 501 999 M-F 9:00 am to 5:00 pm

Purifying Oxygenating Moisturizing Cream

REFERENCIA: AMA20001CR

STAMPING PLATA

PANTONE METALIZADO: 877C



NORMAL, MIXED SKIN.
Specially for skin lacking vitality and luminosity.
PURIFYING HYDRO-OXYGENATING CREAM
with: RIBOXYL®: Stimulates cellular respiration.
HYALURONIC ACID: Wrinkle filler. Firming. Unisex formula. Apply to face and neck after cleansing.

PEAU NORMALE, MIXTE.
Spécialement pour la peau qui manque de vitalité et luminosité.
CRÈME PURIFIANTE HYDRATANTE OXYGÉNANTE contenant : RIBOXYL® : Stimule la respiration cellulaire. ACIDE HYALURONIQUE : Complément de rides. Raffermissant. Formule unisexe. Appliquer tant sur le visage que sur le cou nettoyés.

PIEL NORMAL, MIXTA.
Especialmente para piel con falta de vitalidad y luminosidad.
Doble efecto oxigenante.
CREMA PURIFICANTE HIDRATANTE OXYGENANTE con: RIBOXYL®: Estimula la respiración celular. A. HIALURÓNICO: Rellenador de arrugas. Raffermissante. Fórmula Unisex. Aplicar sobre rostro y cuello limpios.

PELLI NORMALI, MISTE.
Specialmente indicato per pelli prive di vitalità e luminosità.
Doppio effetto ossigenante.
CREMA PURIFICANTE IDRATANTE OSSIGENANTE con: RIBOXYL®: Stimola la respirazione cellulare.
ACIDO IALURONICO: Filler antirughe rassodante. Formula unisex. Applicare su viso e collo precedentemente puliti.

NORMALE, MISCH HAUT.
Speziell für bei mangelnder Vitalität und Leuchtkraft Haut.
Oxygenierende Doppelwirkung.
PURIFYING SAUERSTOFFSPENDENDE FEUCHTIGKEITSCREME mit: RIBOXYL®: regt die Zellatmung an. HYALURONSÄURE: Füllt Falten auf. Strafft die Haut. Unisex Formel. Auf gereinigte Haut von Gesicht und Hals auftragen.

combine with/ à combiner avec/ combinar con
abbinare o /zu kombinieren mit:
OXYGENATING SERUM and/or
OXYGENATING NOURISHING CREAM.
SÉRUM OXYGÉNANT et/ou
CRÈME OXYGÉNANTE NOURRISSANTE.

CASHARA COSMETICS, S.A.
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purifying
OXYGENATING MOISTURIZING CREAM
CRÈME OXYGÉNANTE HYDRATANTE

SKIN PROTECTANT.
HELPS TO PREVENT DEHYDRATION
OF THE SKIN.
Pure Oxygen 01 FACIAL COLLECTION
50 ml. 1.7 fl.oz.

Drug Facts	
Active ingredients	Purpose
Mineral Oil 1.7%	Skin protectant
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PURIFYING OXYGENATING MOISTURIZING CREAM

mineral oil, glycerin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:20151-083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	6.5 mg in 1 mL
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	17 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EGG YOLK (UNII: 4IPS17B70T)	2 mg in 1 mL
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	2 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	0.62 mg in 1 mL
CETYL PHOSPHATE (UNII: VT07D6X67O)	0.625 mg in 1 mL
MACADAMIA OIL (UNII: 515610SU8C)	4.99 mg in 1 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.6 mg in 1 mL
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	0.45 mg in 1 mL
RIBOSE, D- (UNII: 681HV46001)	0.2 mg in 1 mL
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A)	0.1 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.1 mg in 1 mL
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	0.094 mg in 1 mL
TOCOPHEROL (UNII: R0ZB2556P8)	0.002 mg in 1 mL
ASCORBYL PALMITATE (UNII: QN83US2B0N)	0.0005 mg in 1 mL
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	0.011 mg in 1 mL
WATER (UNII: 059QF0K00R)	63.59 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:20151-083-02	1 in 1 CARTON	02/23/2017	
1	NDC:20151-083-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/23/2017	

Labeler - Casmara Cosmetics, SA (464973544)

Registrant - Casmara Cosmetics, SA (464973544)

Establishment

Name	Address	ID/FEI	Business Operations
Casmara Cosmetics, SA		464973544	manufacture(20151-083)

Revised: 2/2017

Casmara Cosmetics, SA