

SOFT DERM INTENSIVE DEFENSE 8 SPF - octinoxate, titanium dioxide cream
LABORATORIOS DE COSMETICA SCIENTIFICA ATACHE 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.

SOFT DERM INTENSIVE DEFENSE 8 SPF

CALMING FACIAL EMULSION DAY

Balanced facial emulsion. Specifically created for the care of sensitive skin, with effects that are relaxing, cleaning, restoring, and protective.

Directions: After cleansing and toning the skin, gently massage into the skin until fully absorbed.

Warnings: For external use only. Keep out of reach of children. Avoid contact with eyes. Discontinue use if signs of irritation or rash appear.

ACTIVE INGREDIENTS:

OCTINOXATE 20% - sunscreen

TITANIUM DIOXIDE 14% - sunscreen

OTHER INGREDIENTS: AQUA (THERMAL WATER), ICTYLDODECYL MYRISTATE, PEG-6 STEARATE, GLYCERIN, C12-15 ALKYL BENZOATE, CETYL ALCOHOL, DIMETHICONE, ALOE BARBADENSIS GEL 10:1, CAPPARIS SPINOSA FRUIT EXTRACT, HYDROLYZED ENTEROMORPHA COMPRESSA EXTRACT, CETETH-20, GLYCERYL STEARATE, STEARETH-20, XANTUAN GUM, ALLANTOIN, BUTYLENE GLYCOL, ALUMINUM STEARATE, POLYHYDROXYSTEARIC ACID, ALUMINUM OXIDE, DISODIUM EDTA, PHENOXYETANOL, METHYLPARABEN, BUTYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, ISOBUTYLPARABEN, DIMENTICONE CROSSPOLYMER, BHT, PERFUM.



SOFT  DERM

INTENSIVE DEFENSE
8 SPF

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CALMING FACIAL EMULSION DAY
EMULSION CALMANTE VISAGE JOUR
EMULSIONE CALMANTE VISO GIORNO

50 ml e 1.69 FL OZ

SOFT DERM INTENSIVE DEFENSE 8 SPF

octinoxate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75870-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	10 mL in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM - UNII:D1JT611TNE)	TITANIUM DIOXIDE	7.045 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
OCTYLDODECYL MYRISTATE (UNII: S013N99GR8)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CAPER BERRY (UNII: 7G4C45EE8C)	
CAPSOSIPHON FULVESCENS (UNII: C59NK6GFJH)	
CETETH-20 (UNII: I835H2IHHX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARETH-20 (UNII: L0Q8IK9E08)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALLANTOIN (UNII: 344S277G0Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	
ALUMINUM OXIDE (UNII: LM26O6933)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
BUTYLPARABEN (UNII: 3QP1I03FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
WATER (UNII: 059QF0K00R)	
ULVA COMPRESSA PROTEIN (ACID HYDROLYZED, 300-5000 MW) (UNII: Q04O53779D)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75870-002-02	1 in 1 CARTON		

1	NDC:75870-002-01	50 mL in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	07/01/2007		

Labeler - LABORATORIOS DE COSMETICA SCIENTIFICA ATACHE SA (467582193)

Establishment			
Name	Address	ID/FEI	Business Operations
LABORATORIOS DE COSMETICA SCIENTIFICA ATACHE SA		467582193	manufacture

Revised: 6/2011

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