

FIRMING AND MOISTURIZING BODY- octinoxate emulsion
Zenith Medicosm SL

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.

Drug Facts

Active Ingredient

Octinoxate 7.5%

Description

SUN CARE CREAM FOR BODY

SPF 25

MEDIUM PROTECTION

UVA - UVB - WATER RESISTANT

Body emulsion rich in anti-age ingredients. Its formula protects skin from UVB and UVA rays while moisturizing and reaffirming the skin (collagen, aloe vera, green tea). Easy to apply for even, translucent coverage. Water resistant.

150ml. 5Fl.Oz.

Warning

TOPICAL USE / PROFESSIONAL ONLY

Instructions for use

Apply a considerable amount on entire body every day, with special emphasis on dry and damaged areas (legs, elbows, knees). Massage gently into the skin until completely absorbed

oceamar

BODY CARE

Firming & Moisturizing

Body Emulsion

SPF 8

[ZENITH]
MEDICAL COSMETICS

Exclusiva emulsión corporal que combina un alto poder reafirmante e hidratante y una dosis de energía. Enriquecida con reafermine, colágeno marino, y seda primavera. Su textura suave y rica aporta un perfecto equilibrio de bienestar y protección frente a los agentes externos.

Modo de empleo: Aplicar diariamente por todo el cuerpo. Extender una abundante cantidad, insistiendo en las zonas más secas y castigadas (piernas, codos, rodillas). Realizar un suave masaje hasta lograr su total absorción.

Exclusive body emulsion with high reaffirming and moisturizing properties, plus a dose of energy. Enriched with a raffermine, marine collagen and silk proteins. Its smooth, rich texture provides the perfect balance between wellbeing and protection against external agents.

Instructions for use: Apply a considerable amount on your entire body every day, with special emphasis on dry and damaged areas (legs, elbows, knees). Massage gently into the skin until completely absorbed.

Ingredients: AQUA (WATER), PROPYLENE GLYCOL, CETEARYL ISONONAOATE, CETEARYL ALCOHOL, ETHYLHEXYL METHOXYCINNAMATE, PEG-6 STEARATE, PEG-8 STEARATE, STEARIC ACID, ISOPROPYL PALMITATE, UREA, ARNICA MONTANA (ARNICA EXTRACT), ALOE BARBADENSIS (ALOE EXTRACT), PEG-32 STEARATE, CAMELIA SINENSIS (GREEN TEA EXTRACT), DIMETHICONE, CORYLUS AVELLANA (HAZELNUT OIL), OLEA EUROPAEA (OLIVE OIL), HYDROLYZED SILK, SILK, BUTYL METHOXYDIBENZOYLMETHANE, CUCUMIS SATIVUS (CUCUMBER EXTRACT), ALLANTOIN, LAMINARIA DIGITATA, TRIETHANOLAMINE, GLYCINE MAX (SOYBEAN EXTRACT), HYDROLYZED LUPIN PROTEIN, TRITICUM VULGARE (WHEAT PROTEIN), SOLUBLE COLLAGEN, PHOSPHOLIPIDS, CHONDRUS CRISPUS (CARRAGEENANS), CARBOMER, LECITHIN, GLYCOLIPIDS, EDTA, PHENOXYETHANOL, METHYLPARABEN, BUTYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, ISOBUTYLPARABEN, IMIDAZOLIDINYL UREA, PARFUM (FRAGRANCE).

TOPICAL USE / PROFESSIONAL ONLY



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Zenith Medicosm S.L.

C. Buenos Aires, 37- 08759 Barcelona (Spain)

250 ml. PRODUCT OF EU 8,5 FL.Oz.

FIRMING AND MOISTURIZING BODY

octinoxate emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-132
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	18.75 mL in 250 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PEG-6 STEARATE (UNII: 8LQC57C6B0)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETEARYL ISONONANOATE (UNII: P5O01U99N1)	
SOYBEAN (UNII: L7HT8F1ZOD)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
CARBOMER HOMOPOLYMER TYPE B/C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLPARABEN (UNII: 3QP1I3FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
PEG-32 STEARATE (UNII: 33GX5WQC0M)	
EUROPEAN HAZELNUT OIL (UNII: 8RQ2839AVG)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
EDETIC ACID (UNII: 9G34HU7RV0)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CUCUMBER (UNII: YY7C30VXJT)	
UREA (UNII: 8W8T17847W)	
ARNICA MONTANA (UNII: O80TY208ZW)	
IMIDUREA (UNII: M629807ATL)	
BOMBYX MORI FIBER (UNII: 6LK42KUV6W)	

FISH SKIN COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-132-01	250 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/15/2011	

Labeler - Zenith Medicosm SL (464239694)

Registrant - Zenith Medicosm SL (464239694)

Establishment

Name	Address	ID/FEI	Business Operations
Zenith Medicosm SL		464239694	manufacture

Revised: 5/2012

Zenith Medicosm SL