

# REGEMARINE EXTREME- octinoxate cream

## 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%

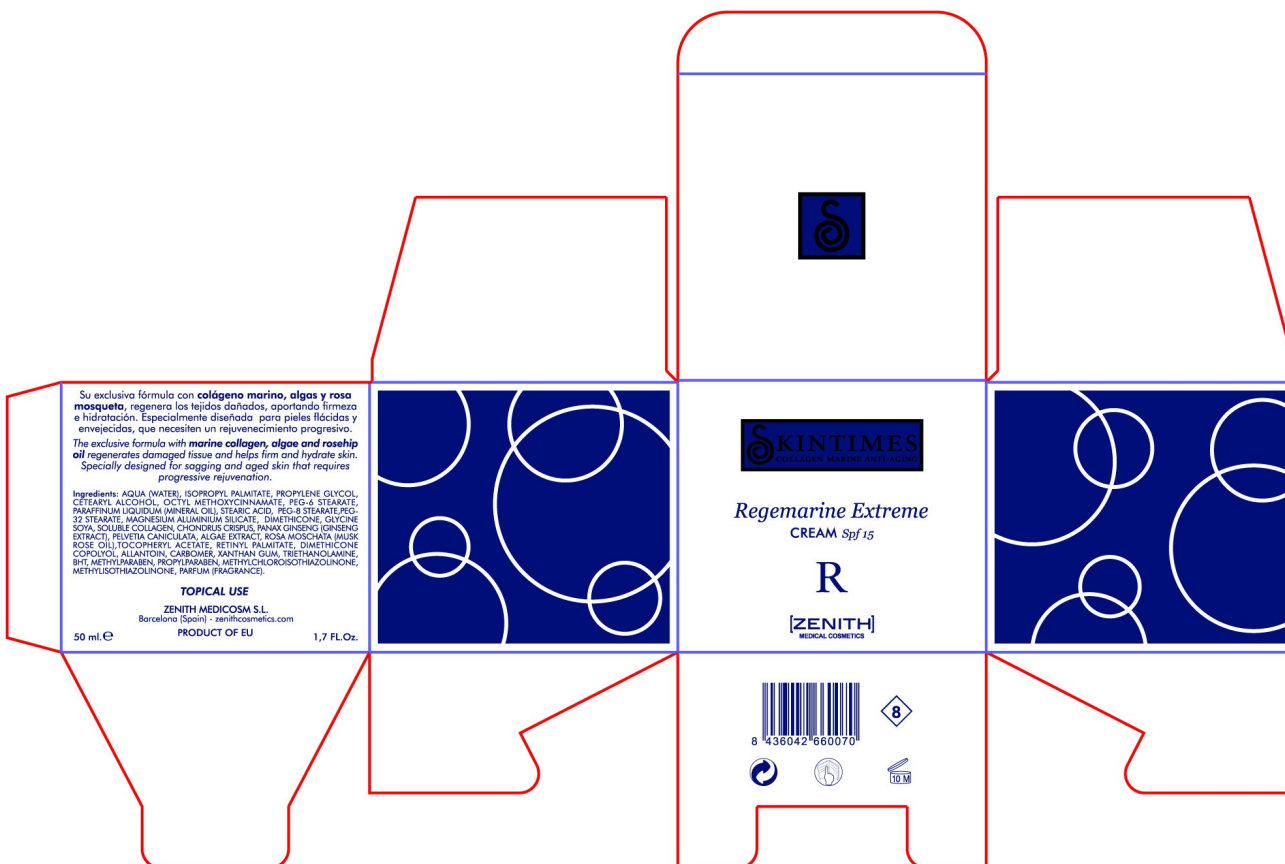
### Description

The exclusive formula with marine collagen, algae and rosehip oil regenerates damaged tissue and helps firm and hydrate skin. Specially designed for sagging and aged skin that requires progressive rejuvenation.

50ml. 1.7 fl. Oz

### Warning

**TOPICAL USE**



# REGEMARINE EXTREME

octinoxate cream

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:42248-107 |
| Route of Administration | TOPICAL        |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength         |
|--|-------------------|------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE        | 3.75 mL in 50 mL |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)  |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)     |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                  |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                  |          |
| ROSA MOSCHATA OIL (UNII: J99W255AWF)            |          |
| WATER (UNII: 059QF0KO0R)                        |          |
| MINERAL OIL (UNII: T5L8T28FGP)                  |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)          |          |
| PEG-8 STEARATE (UNII: 2P9L47VI5E)               |          |
| TROLAMINE (UNII: 9O3K93S3TK)                    |          |
| SOYBEAN (UNII: L7HT8F1ZOD)                      |          |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X)             |          |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)     |          |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)        |          |
| CARBOMER 934 (UNII: Z135WT9208)                 |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)             |          |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)  |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)                |          |
| COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W) |          |
| ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)          |          |
| PEG-6 STEARATE (UNII: 8LQC57C6B0)               |          |
| PEG-32 STEARATE (UNII: 33GX5WQC0M)              |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                 |          |
| PANAX GINSENG FRUIT (UNII: E35T4MOIBE)          |          |
| PEG/PPG-20/23 DIMETHICONE (UNII: XK68QT7HWY)    |          |
| FUCUS VESICULOSUS (UNII: 535G2ABX9M)            |          |
| PELVETIA CANALICULATA (UNII: 8U1M44KESN)        |          |
| ALLANTOIN (UNII: 344S277G0Z)                    |          |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)          |          |

## Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42248-107-02 | 1 in 1 BOX          |                      |                    |
| 1 |                  | 50 mL in 1 JAR      |                      |                    |

| 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: 1/2012

Zenith Medicosm SL