

# HYDROMARINE 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%

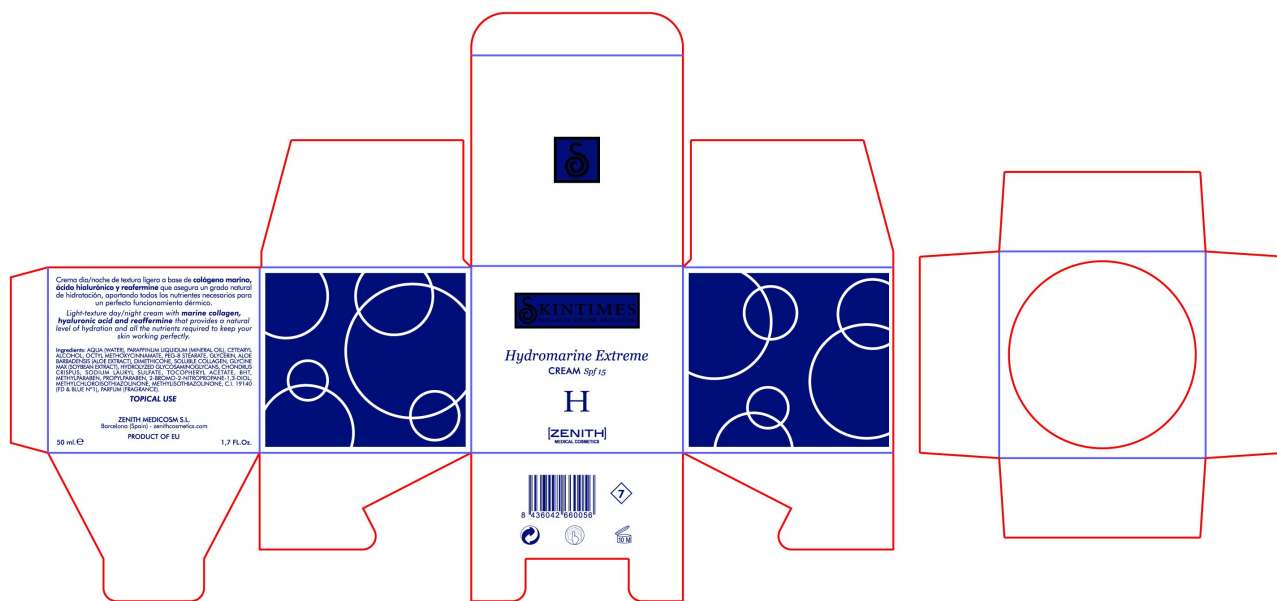
### Description

Light-texture day/night cream with marine collagen, hyaluronic acid and reaferrmine that provides a natural level of hydration and all the nutrients required to keep your skin working perfectly.

50ml. 1.7 fl. Oz

### Warning

TOPICAL USE



## HYDROMARINE EXTREME

octinoxate cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:42248-101 |
| <b>Route of Administration</b> | 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 |
|---|----------|
| ALOE (UNII: V5VD430YW9)   |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                                    |          |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)                         |          |
| GLYCERIN (UNII: PDC6A3C0OX)   |          |
| TRICHLOROETHANE (UNII: 113C650IR1)                                  |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                            |          |
| WATER (UNII: 059QF0KO0R)  |          |
| MINERAL OIL (UNII: T5L8T28FGP)                                      |          |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)                              |          |
| PEG-8 STEARATE (UNII: 2P9L47VI5E)                                   |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                                      |          |
| SOYBEAN (UNII: L7HT8F1ZOD)  |          |
| CHONDRUS CRISPUS (UNII: OQS23HUA1X)                                 |          |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                         |          |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)                                    |          |
| BRONOPOL (UNII: 6PU1E16C9W)   |          |
| HYDROLYZED GLYCOSAMINOGLYCANS (BOVINE; 50000 MW) (UNII: 997385V0VV) |          |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)                      |          |
| METHYLPARABEN (UNII: A2I8C7HI9T)                                    |          |
| COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)                     |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                                  |          |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42248-101-02 | 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)