

# SEBORRHEIC PURIFYING- 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%

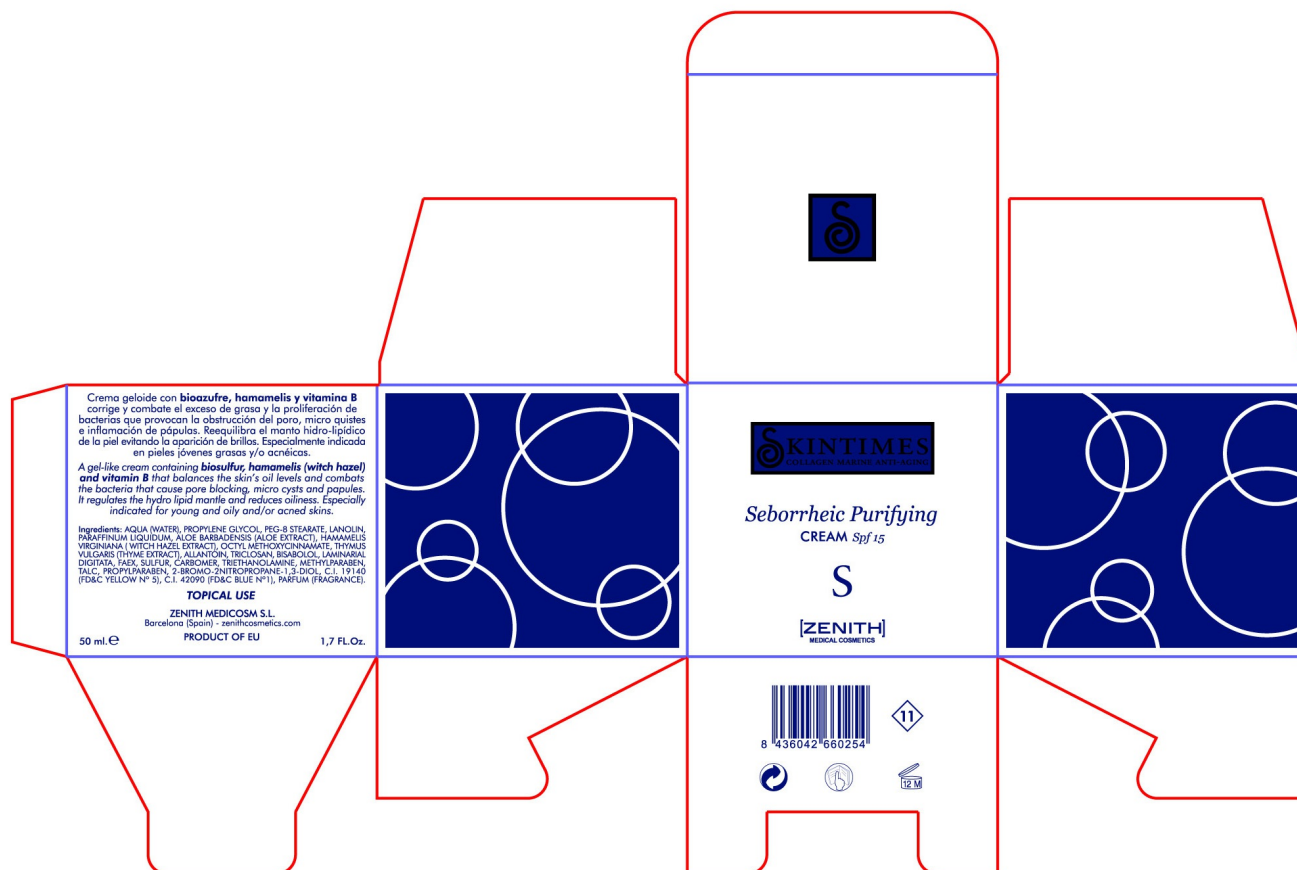
### Description

A gel-like cream containing biosulfur, hamamelis (witch hazel) and vitamin B that balances the skin's oil levels and combats the bacteria that cause pore blocking, micro cysts and papules. It regulates the hydro lipid mantle and reduces oiliness. Especially indicated for young and oily and/or acned skins.

50ml. 1.7 fl. Oz

### Warning

**TOPICAL USE**



# SEBORRHEIC PURIFYING

octinoxate cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42248-108
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
LANOLIN (UNII: 7EV65EAW6H)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
TALC (UNII: 7SEV7J4R1U)	
THYME (UNII: CW657OBU4N)	
ALOE (UNII: V5VD430YW9)	
HAMAMELIS VIRGINIANA LEAF (UNII: T07U1161SV)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
TRICLOSAN (UNII: 4NM5039Y5X)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
TROLAMINE (UNII: 9O3K93S3TK)	
LEVOMENOL (UNII: 24WE03BX2T)	
SULFUR (UNII: 70FD1KFU70)	
YEAST (UNII: 3NY3SM6B8U)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
CARBOMER 934 (UNII: Z135WT9208)	
ALLANTOIN (UNII: 344S277G0Z)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
COLLAGEN, SOLUBLE, FISH SKIN (UNII: 8JC99XGU4W)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42248-108-02	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
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OTC monograph not final	part352	08/15/2011	
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**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