

INTROSTEM STEM CELL ACTIVE DEFENSE- octinoxate, homosalate, octisalate, oxybenzone and avobenzone cream
Lionesse USA, Inc.

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.

Introstem® Stem Cell Active Defense Cream

Active Ingredients

Octinoxate 7.40%
Homosalate 6.20%
Octisalate 5.00%
Oxybenzone 3.10%
Avobenzone 1.50%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

For external use only. Do not use on damaged or broken skin.

Keep out of eyes. If contact occurs, rinse with water. If rash or irritation develops, discontinue use and consult your physician.

Stop using this product

and ask doctor if rash or redness develops and lasts.

Keep out of reach of children.

If accidental ingestion, call the Poison Control Center right away.

Directions

- After cleansing, apply liberally and evenly 15 minutes before sun exposure. Smooth over face and neck and chest daily for optimal results.
- Reapply at least every two (2) hours.

- Use water resistant sunscreen if swimming or sweating.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses

For children under 6 months of age: Ask doctor.

Other Information

Protect the product in this container from excessive heat and direct sun. Store at room temperature.

Inactive Ingredients

Aqua, C12-15 Alkyl Benzoate, Glycerin, Glyceryl Stearate, Stearic Acid, PEG-100 Stearate, Phenoxyethanol, Ethylhexylglycerin, Polysorbate 60, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Triethanolamine, Fragrance, Tocopherol, Retinyl Palmitate, Aloe Barbadensis Leaf Extract, Camellia Sinensis Extract, Sodium PCA, Vitis Vinifera (Grape) Fruit Cell Extract, Disodium EDTA.

Package/Label Principal Display Panel

INTROSTEM®

STEM CELL ACTIVE DEFENSE
Dèfense Active Cellules Souches SPF 30
BROAD SPECTRUM SPF 30

infused with grape stem extract

50g | 1.76oz

www.introstem.com
20255 Corisco St.
Chatsworth, CA 91311



Label

INTROSTEM STEM CELL ACTIVE DEFENSE			
octinoxate, homosalate, octisalate, oxybenzone and avobenzone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72104-589
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	7.4 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	6.2 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	5.0 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)		OXYBENZONE	3.1 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	1.5 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
TOCOPHEROL (UNII: R0ZB2556P8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
WINE GRAPE (UNII: 3GOV20705G)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72104-589-83	1 in 1 CARTON	07/27/2021	
1		50 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/27/2021	

Labeler - Lionesse USA, Inc. (079661431)

Revised: 7/2022

Lionesse USA, Inc.