

HARD CANDY CORRECTION CREME- octinoxate, octisalate cream
Xtreme Color 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.

Hard Candy Correction Creme
Broad Spectrum SPF-15

For external use only.

Do not use on damaged or broken skin.

When using this product keep out of eyes.

Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Folding Carton Artwork.jpg



HARD CANDY CORRECTION CREME

octinoxate, octisalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58875-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	Octinoxate	2.55 g in 42.5 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	1.7 g in 42.5 g

Inactive Ingredients				
Ingredient Name			Strength	
DIMETHICONE (UNII: 92RU3N3Y1O)			5.15525 g in 42.5 g	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)			2.55425 g in 42.5 g	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)			1.27925 g in 42.5 g	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)			1.1333 g in 42.5 g	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			0.189 g in 42.5 g	
FERRIC OXIDE RED (UNII: 1K09F3G675)			1.1333 g in 42.5 g	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)			1.1333 g in 42.5 g	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)			0.0425 g in 42.5 g	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			1.0115 g in 42.5 g	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)			0.85 g in 42.5 g	
TRIBEHENIN (UNII: 8OC9U7TQZ0)			2.89425 g in 42.5 g	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			2.171113 g in 42.5 g	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)			0.255425 g in 42.5 g	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)			0.127713 g in 42.5 g	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			0.0425 g in 42.5 g	
PHENOXYETHANOL (UNII: HIE492ZZ3T)			0.17595 g in 42.5 g	
SORBIC ACID (UNII: X045WJ989B)			0.02125 g in 42.5 g	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			0.1428 g in 42.5 g	
ISODODECANE (UNII: A8289P68Y2)			1.70425 g in 42.5 g	
WATER (UNII: 059QF0KO0R)			13.68625 g in 42.5 g	
GLYCERIN (UNII: PDC6A3C0OX)			1.27925 g in 42.5 g	
SODIUM CHLORIDE (UNII: 451W47IQ8X)			0.425 g in 42.5 g	
MICA (UNII: V8A1AW0880)			0.195 g in 42.5 g	
CHROMIC OXIDE (UNII: X5Z09SU859)			.006 g in 42.5 g	
FERRIC FERROCYANIDE (UNII: TLE294X33A)			.001 g in 42.5 g	
CARMINIC ACID (UNII: CID8Z8N95N)			.003 g in 42.5 g	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)			0.425 g in 42.5 g	
STEARETH-2 (UNII: V56DFE46J5)			0.2125 g in 42.5 g	
Product Characteristics				
Color	brown	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58875-101-01	42.5 g in 1 TUBE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part352	06/12/2013	

Labeler - Xtreme Color Inc. (628045858)

Establishment			
Name	Address	ID/FEI	Business Operations
NuWorld Corporation		628045858	manufacture(58875-101) , pack(58875-101) , label(58875-101)

Revised: 8/2013

Xtreme Color Inc.