

XXL SUN BLOCK SPF 50- octinoxate, octocrylene, octisalate, avobenzone, homosalate, titanium dioxide cream cream

Peer Pharma Ltd.

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.

Gold Cosmetics XXL Sun Block SPF 25



Octinoxate 7%

Octocrylene 5%

Octisalate 5%

Avobenzone 3%

Homosalate 2%

Titanium Dioxide 3%

Keep out of reach of children.

Provides SPF 50 protection

Directions for Use: Apply generously to face and body regularly before sun exposure and as needed.

Reapply: after 40 minutes before of or 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours.

Directions for Use: Apply generously to face and body regularly before sun exposure and as needed.

Reapply: after 40 minutes before of or 80 minutes of swimming or sweating, immediately after towel drying, and at least every 2 hours.

XXL SUN BLOCK SPF 50

octinoxate, octocrylene, octisalate, avobenzone, homosalate, titanium dioxide cream cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1804
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2 g in 100 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALMOND OIL (UNII: 66YXD4DKO9)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALLANTOIN (UNII: 344S277G0Z)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PUNICA GRANATUM ROOT BARK (UNII: CLV243T1D)	
SHEA BUTTER (UNII: K49155WL9Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
NIACINAMIDE (UNII: 25X5118RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SEA SALT (UNII: 87GE52P74G)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
WATER (UNII: 059QF0KO0R)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1804-1	100 mL in 1 CONTAINER; Type 0: Not a Combination Product	05/24/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/24/2018	

Labeler - Peer Pharma Ltd. (514678390)

Registrant - Peer Pharma Ltd. (514678390)

Establishment

Name	Address	ID/FEI	Business Operations
Peer Pharma Ltd.		514678390	manufacture(69435-1804)

Revised: 5/2018

Peer Pharma Ltd.