

XXL DEMI MAKE UP 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 Demi Make Up SPF 50

GOLD
cosmetics
Adi & Skin Care Or

XXL

DEMI MAKE UP
SPF 50

3.4fl. oz. e 100ml

Drug Facts
Active ingredient:
Homosalate 10
Octinoxate 7.5
Octisalate 5
Octocrylene 5
Titanium Dioxide 3
Avobenzone 3

Use: Skin coverage with Sunscreen.

Warnings: For external use only. **Do not use** on damaged or broken skin. Do not use if you have known sensitivities to any one of the ingredients. **When using this product** avoid contacts with eyes. If contact occurs, rinse eyes thoroughly with water. **Stop use and ask a doctor** if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately. This cosmetic product should be used only for the purpose it was intended and according to its instructions. **Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging.

Directions for use: gently apply "gold" demi makeup to Face and neck prior to sun exposure for instant Coverage and correction as well as for protection. Reapply as needed.

Inactive Ingredients: Water (Aqua), Behenyl Alcohol, Propylene Glycol, Cetyl Alcohol, Potassium Cetyl Phosphate, Polyglyceryl-10 Pentaisostearate, Dimethicone, Sodium Stearoyl Lactylate, Nylon-12, Fragrance (Parfum), Benzyl Alcohol, Aloe Barbadensis Leaf Juice, Allantoin, Benzoic Acid, Citric Acid, Dehydroacetic Acid, Tocopherol, Lecithin, Ascorbyl Palmitate, Glyceryl Oleate, Glyceryl Stearate, Iron Oxides (CI 77491, CI77492).

MADE IN IL
GOLD COSMETICS
& SKIN CARE
1118 AVE. J
BROOKLYN, NY 11230
TEL: 718-677 7711

907xxx
ITEM #8217
7290110808174

Octinoxate 7%

Octocrylene 5%

Octisalate 5%

Avobenzone 3%

Homosalate 2%

Titanium Dioxide 3%

Keep out of reach of children.

Provides SPF 50 protection

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69435-1803
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
NYLON-12 (UNII: 446U8J075B)	
ALLANTOIN (UNII: 344S277G0Z)	
DOCOSANOL (UNII: 9G1OE216XY)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETEARYL GLUCOSIDE (UNII: 09FUA47KNA)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POLYGLYCERIN-10 (UNII: P9060O936A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69435-1803-1	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(69435-1803)

Revised: 5/2018

Peer Pharma Ltd.