

BREATHABLE CONCEALER LIGHT- titanium dioxide and zinc oxide cream
BREATHABLE CONCEALER MEDIUM- titanium dioxide and zinc oxide cream
BREATHABLE CONCEALER TAN- titanium dioxide and zinc oxide cream
Quura Medical B.V

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.

Actives :

Titanium Dioxide
Zinc Oxide

Inactives

Cyclopentasiloxane,Zinc Oxide,Dimethicone,Titanium Dioxide,Bismuth Oxychloride,Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone
Water (Aqua),Mica,Dimethicone/PEG-10/15 Crosspolymer,Hydroxypropylcocoate PEG-8 Dimethicone,Polyglyceryl-2 Diisostearate, Stearic Acid,Aluminum Hydroxide,Dimethicone/Vinyl Dimethicone Crosspolymer,Glycerin,Saccharomyces Lysate Extract,Cyclotetrasiloxane,Cyclohexasiloxane,Sodium Hyaluronate,Santalum Album (Sandalwood) Extract,Algae Extract,Centella Asiatica Extract,Artemisia Vulgaris Extract,Isohexadecane,Hydrated Silica,Malus Domestica Fruit Cell Culture,Hordeum Distichon (Barley) Extract,Lonicera Japonica (Honeysuckle) Flower Extract,PEG/PPG-18/18 Dimethicone,Xanthan Gum,Lecithin,Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone,Cyperus Rotundus Root Extract,Xanthium Sibiricum Fruit Extract,Phospholipids ,Olea Europaea (Olive) Leaf Extract,Mannitol,Sodium Benzoate,Ascorbyl Palmitate,Retinyl Palmitate,Squalane,Zinc PCA,Sodium Citrate,Acetyl Tetrapeptide-15,Tocopherol,Triethoxycaprylylsilane,Phellodendron Amurense Bark Extract,Beta-Carotene,Phenoxyethanol,Ethylhexylglycerin,Hexylene Glycol, Caprylyl Glycol,Iron Oxides (CI 77492),Iron Oxides (CI 77491),Iron Oxides (CI 77499),Titanium Dioxide (CI 77891)

Tube Label

992401
Lycogel[®]

BREATHABLE
CONCEALER

SPF 30

Tube label 2



Outer Label



BREATHABLE CONCEALER LIGHT

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL

Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)

Titanium Dioxide

64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0K00R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SANDALWOOD (UNII: 3641YW25N2)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
ISOHEXADECANE (UNII: 918X10UF1E)	
Hydrated Silica (UNII: Y6O7T4G8P9)	
APPLE (UNII: B423VGH5S9)	
BARLEY (UNII: 5PWM7YLI7R)	
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)	
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SQUALANE (UNII: GW89575KF9)	
ZINC PIDOLATE (UNII: C32PQ86DH4)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

Product Characteristics			
Color	white (Titanium Dioxide) , red (FERRIC OXIDE RED)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-100-01	7.4 mL in 1 TUBE; Type 0: Not a Combination Product	12/07/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/07/2017	

BREATHABLE CONCEALER MEDIUM

titanium dioxide and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL	
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
DIMETHICONE (UNII: 92RU3N3Y10)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
WATER (UNII: 059QF0KO0R)	
MICA (UNII: V8A1AW0880)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	

STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
GLYCERIN (UNII: PDC6A3C0OX)
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SANDALWOOD (UNII: 3641YW25N2)
CHLORELLA VULGARIS (UNII: RYQ4R60M02)
CENTELLA ASIATICA (UNII: 7M867G6T1U)
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)
ISOHEXADECANE (UNII: 918X1OUF1E)
Hydrated Silica (UNII: Y6O7T4G8P9)
APPLE (UNII: B423VGH5S9)
BARLEY (UNII: 5PWM7YL17R)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
XANTHAN GUM (UNII: TTV12P4NEE)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SQUALANE (UNII: GW89575KF9)
ZINC PIDOLATE (UNII: C32PQ86DH4)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
Phenoxyethanol (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Product Characteristics

Color	white (Titanium Dioxide) , red (FERRIC OXIDE RED)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:51790-101-01	7.4 mL in 1 TUBE; Type 0: Not a Combination Product	12/07/2017
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/07/2017	

BREATHABLE CONCEALER TAN
titanium dioxide and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	86 mg in 1 mL
	Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	64 mg in 1 mL

Inactive Ingredients	
	Ingredient Name
	CYCLOMETHICONE 5 (UNII: 0THT5PC10R)
	DIMETHICONE (UNII: 92RU3N3Y1O)
	BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
	POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPAS) (UNII: RLA2U05Z4Q)
	WATER (UNII: 059QF0KO0R)
	MICA (UNII: V8A1AW0880)
	CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
	HYDROXYPROPYLCOCOATE PEG-8 DIMETHICONE (UNII: 8TE0BZU36S)
	POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)
	STEARIC ACID (UNII: 4ELV7Z65AP)
	ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
	GLYCERIN (UNII: PDC6A3C0OX)
	SACCHAROMYCES LYSATE (UNII: R85W246Z1C)
	CYCLOMETHICONE 6 (UNII: XHK3U310BA)
	HYALURONATE SODIUM (UNII: YSE9PPT4TH)
	SANDALWOOD (UNII: 3641YW25N2)
	CHLORELLA VULGARIS (UNII: RYQ4R60M02)
	CENTELLA ASIATICA (UNII: 7M867G6T1U)
	ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)
	ISOHEXADECANE (UNII: 918X10UF1E)
	Hydrated Silica (UNII: Y6O7T4G8P9)
	APPLE (UNII: B423VGH5S9)

BARLEY (UNII: 5PWM7YLI7R)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
XANTHAN GUM (UNII: TTV12P4NEE)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CYPERUS ROTUNDUS ROOT (UNII: 4B51SRR959)
XANTHIUM SIBIRICUM WHOLE (UNII: H05ZV0N61A)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
MANNITOL (UNII: 3OWL53L36A)
SODIUM BENZOATE (UNII: OJ245FE5EU)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SQUALANE (UNII: GW89575KF9)
ZINC PIDOLATE (UNII: C32PQ86DH4)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
TOCOPHEROL (UNII: R0ZB2556P8)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHELLODENDRON AMURENSE BARK (UNII: PBG27B754G)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
Phenoxyethanol (UNII: HIE492ZZ3T)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)

Product Characteristics

Color	white (Titanium Dioxide) , red (FERRIC OXIDE RED)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-102-01	7.4 mL in 1 TUBE; Type 0: Not a Combination Product	12/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/07/2017	

Labeler - Quura Medical B.V (489419151)

Establishment

Name	Address	ID/FEI	Business Operations
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Allure Cosmetic Inc.

926831603

manufacture(51790-100, 51790-101, 51790-102)

Revised: 12/2017

Quura Medical B.V