

**LYCOGEL BREATHABLE BALM- octinoxate,oxybenzone,octisalate and avobenzone 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

OCTINOXATE,OXYBENZONE,OCTISALATE and AVOBENZONE

Inactives

Water (Aqua)

C12-15 Alkyl Benzoate

Octinoxate

Oxybenzone

Octisalate

Butylene Glycol

Octyldodecyl Neopentanoate

Caprylic/Capric Triglyceride

Avobenzone

Octocrylene

Glycerin

Sodium Hyaluronate

Camellia Sinensis Leaf Extract

Teprenone

Cyclopentasiloxane

Cyclohexasiloxane

Actinidia Chinensis (Kiwi) Fruit Extract

Algae Extract

Artemisia Vulgaris Extract

Saccharomyces Lysate Extract

Centella Asiatica Extract

Echinacea Purpurea Extract

Yeast Polysaccharides

Carbomer

Acrylates/C10-30 Alkyl Acrylate Crosspolymer

PEG-8

Triethanolamine

Phenoxyethanol
Caprylyl Glycol
Ethylhexylglycerin
Hexylene Glycol
Tocopherol
Ascorbyl Palmitate
Citric Acid
Zinc PCA
Mannitol
Lonicera Japonica (Honeysuckle) Flower Extract
Sodium Citrate
Xanthium Sibiricum Fruit Extract
Aloe Barbadensis Leaf Extract
Cyperus Rotundus Root Extract
Acetyl Tetrapeptide-15
Sodium Benzoate
Sorbitan Oleate
Polysorbate 20
Palmitoyl Pentapeptide-4
Arctostaphylos Uva Ursi Leaf Extract
Plankton Extract
Mitracarpus Scaber Extract
Olea Europaea (Olive) Leaf Extract
Darutoside
Xanthan Gum
Micrococcus Lysate
Arabidopsis Thaliana Extract
Ubiquinone
Hydroxydecyl Ubiquinone
Disodium EDTA
Phospholipids
Retinyl Palmitate
Beta-Carotene
Ascorbic Acid
Malus Domestica Fruit Cell Culture Extract
Lecithin

Tube Label

Energize and protect your skin
with this clear balm that's packed
with health benefits.

Apply a small amount of
product to fingertips and
spread evenly on skin.
Reapply as needed.

ACTIVE INGREDIENTS

7.5% Octinoxate,
6.0% Oxybenzone,
5.0% Octisalate,
2.0% Avobenzone,
1.5% Octocrylene.

INGREDIENTS

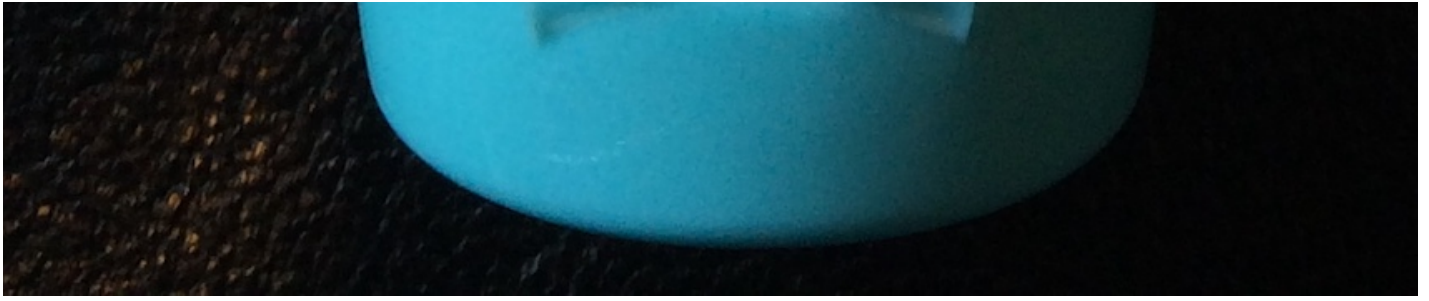
See secondary packaging.

Manufactured for
Quura Medical BV,
1271 GK NL
Made in USA

LYCOGEL.COM

LYCO™
COMPLEX

60ml e Nt Wt 2 fl oz



Tube label 2



BREATHABLE
BALM

SPF 15

LYCOGEL BREATHABLE BALM

octinoxate,oxybenzone,octisalate and avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51790-400
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	60 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TEPRENONE (UNII: S8S8451A4O)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
CYCLOMETHICONE 4 (UNII: CZ227117JE)	
KIWI FRUIT (UNII: 71ES77LGJC)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
ARTEMISIA VULGARIS WHOLE (UNII: JDR81QW9ZQ)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
HEXYLENE GLYCOL (UNII: KEH0A3F75J)
TOCOPHEROL (UNII: R0ZB2556P8)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
ZINC PIDOLATE (UNII: C32PQ86DH4)
MANNITOL (UNII: 3OWL53L36A)
LONICERA JAPONICA FLOWER (UNII: 4465L2WS4Y)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
XANTHIUM SIBIRICUM FRUIT (UNII: 3H33L84C2)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
CYPERUS ROTUNDUS TUBER (UNII: 4B51SRR959)
ACETYL TETRAPEPTIDE-15 (UNII: 6K389LE0MV)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)
ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)
DARUTOSIDE (UNII: EG8ODI0780)
XANTHAN GUM (UNII: TTV12P4NEE)
ARABIDOPSIS THALIANA (UNII: A1BL60HQ81)
UBIDECARENONE (UNII: EJ27X76M46)
IDEBENONE (UNII: HB6PN45W4J)
EDETATE DISODIUM (UNII: 7FLD91C86K)
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
.BETA.-CAROTENE (UNII: 01YAE03M7J)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
APPLE (UNII: B423VGH5S9)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51790-400-01	60 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
Allure Cosmetic Inc.		926831603	manufacture(51790-400)

