

**LIPIDOL- avobenzone, homosalate, octisalate, octocrylene oil
UNION-SWISS (PTY) 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.

Active Ingredients

Purpose

Avobenzone 3%

Homosalate 6%

Octisalate 5%

Octocrylene 6.5% Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Lipidol

Sunscreen Broad Spectrum SPF 20

4.2 fl. oz.

Directions

apply liberally 15 minutes before sun exposure

reapply:

- at least every 2 hours
- immediately after towel drying

use a water resistant sunscreen if swimming or sweating

children under 6 months: Ask a doctor

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m.-2p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

Warnings

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.

Inactive Ingredients

mineral oil (paraffinum liquidum), isopropyl palmitate, cetearyl ethylhexanoate, C12-15 alkyl benzoate, oryxanol, bisabolol, tocopheryl acetate, pyridoxine dipalmitate, octyldodecyl PCA, phytosterols, carthamus tinctorius (safflower) seed oil, borago officinalis (borage) seed oil, linoleic acid, linolenic acid, butylene glycol, BHT, cupressus sempervirens oil, ocimum basilicum (basil) oil, melia azadirachta

leaf extract, melia azadirachta flower extract, aspartic acid, arginine, glycine, glutamic acid, histidine, coccinia indica fruit extract, solanum melongena (eggplant) fruit extract, aloe barbadensis flower extract, lawsonia inermis (henna) flower/fruit/leaf extract, ocimum sanctum leaf extract, ocimum basilicum (basil) flower/leaf extract, curcuma longa (turmeric) root extract, corallina officinalis extract, simmondsia chinensis (jojoba) seed oil, farnesol, limonene



LIPIDOL

avobenzone, homosalate, octisalate, octocrylene oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69359-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
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MINERAL OIL (UNII: T5L8T28FGP)
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)
CETEARYL ETHYLHEXANOATE (UNII: 9M64UO4C25)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
GAMMA ORYZANOL (UNII: SST9XCL51M)
LEVOMENOL (UNII: 24WE03BX2T)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PYRIDOXINE DIPALMITATE (UNII: HB49XCT029)
CERAMIDE 1 (UNII: 5THT33P7X7)
.BETA.-SITOSTEROL (UNII: S347WMO6M4)
SAFFLOWER SEED (UNII: 8FCL6A31TX)
BORAGO OFFICINALIS SEED (UNII: 2GXJ790US0)
LINOLEIC ACID (UNII: 9KJL21T0QJ)
LINOLENIC ACID (UNII: 0RBV727H71)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CUPRESSUS SEMPERVIRENS LEAF OIL (UNII: M7QUY89S40)
OCIMUM BASILICUM WHOLE (UNII: P4815JL4O3)
AZADIRACHTA INDICA WHOLE (UNII: MRL4DVG1F6)
ASPARTIC ACID (UNII: 30KYC7MIAD)
ARGININE (UNII: 94ZLA3W45F)
GLYCINE (UNII: TE7660XO1C)
GLUTAMIC ACID (UNII: 3KX376GY7L)
HISTIDINE (UNII: 4QD397987E)
COCCINIA GRANDIS FRUIT (UNII: VLJ6WOT3K5)
SOLANUM MELONGENA WHOLE (UNII: 5DS5EE0N93)
ALOE VERA FLOWER (UNII: 575DY8C1ER)
LAWSONIA INERMIS WHOLE (UNII: W7M7338R56)
OCIMUM TENUIFLORUM WHOLE (UNII: 7OS52KZ33J)
CURCUMA LONGA WHOLE (UNII: W5488JUO8U)
CORALLINA OFFICINALIS (UNII: 4004498D06)
JOJOBA OIL (UNII: 724GKU717M)
FARNESOL (UNII: EB41QIU6JL)
LIMONENE, (+)- (UNII: GFD7C86Q1W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69359-000-00	125 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/07/2014	

Labeler - UNION-SWISS (PTY) LTD (568517499)

Establishment

Name	Address	ID/FEI	Business Operations
COLUMBIA PHARMACEUTICALS (PTY) LTD		539147769	manufacture(69359-000)

Revised: 11/2015

UNION-SWISS (PTY) LTD