

EQUATE MOISTURE SPF 15 LIP BALM- oxybenzone, octinoxate, petrolatum stick
Walmart

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.

Drug Facts

Active ingredient

Octinoxate (7.5%), Oxybenzone (3.5%)

Petrolatum (40.7%)

Purpose

Sunscreen, Sunscreen, Skin Protectant

Keep Out of Reach of Children

If swallowed get medical help or contact a Poison Control Center right away.

Uses

Helps prevent sunburn. Helps prevent and temporarily protects dry, chapped or windburned lips.

Warnings

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 prevent sunburn, not skin cancer or early aging.

For external use only: Stop use and ask a doctor: if rash or irritation develops and lasts.

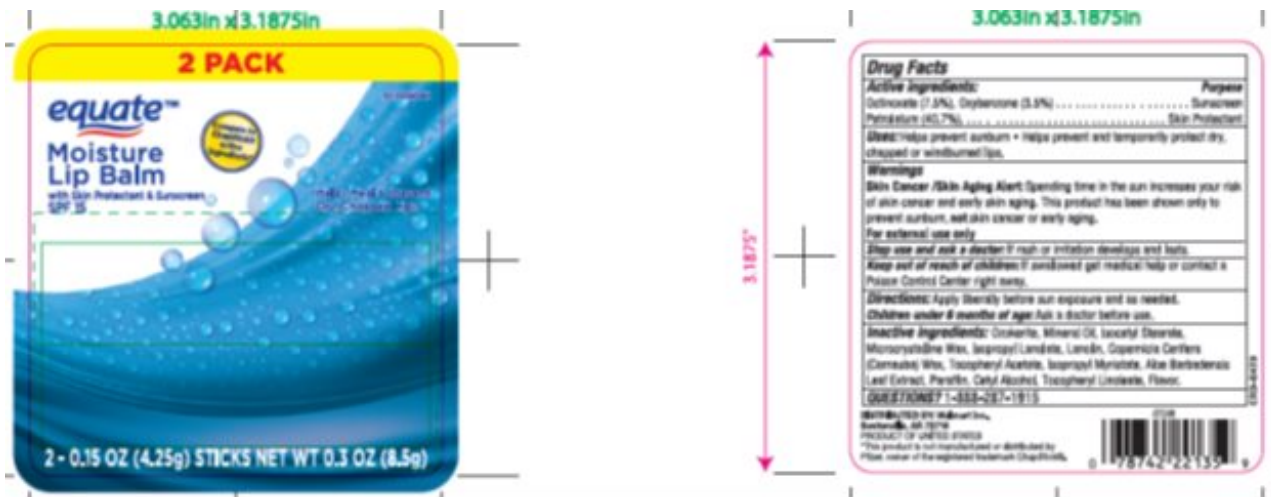
Directions

Apply liberally before sun exposure and as needed. Children under 6 months of age: Ask a doctor before use.

Inactive Ingredients

Ozokerite, Mineral Oil, Isocetyl Stearate, Microcrystalline Wax, Isopropyl Lanolate, Lanolin, Copernicia Cerifera (Carnauba) Wax, Tocopheryl Acetate, Isopropyl Myristate, Aloe Barbadenis Leaf Extract, Paraffin, Cetyl Alcohol, Tocerpheryl Linoleate, Flavor, Methylparaben, Propylparaben.

Package/Label Principal Display Panel



EQUATE MOISTURE SPF 15 LIP BALM

oxybenzone, octinoxate, petrolatum stick

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-665 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 7.5 mg in 1 g |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y) | OXYBENZONE | 3.5 mg in 1 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 40.7 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CERESIN (UNII: Q1LS2UJO3A) | 17.13 mg in 1 g |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | 16.75 mg in 1 g |
| ISOCETYL STEARATE (UNII: 3RJ7186O9W) | 3.50 mg in 1 g |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | 3.00 mg in 1 g |
| LANOLIN (UNII: 7EV65EAW6H) | 1 mg in 1 g |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | .60 mg in 1 g |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49035-665-05 | 1 g in 1 CONTAINER; Type 0: Not a Combination Product | 03/29/2019 | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 03/29/2019 | |

Labeler - Walmart (051957769)

Registrant - OraLabs (801824756)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------|---------|-----------|---|
| OraLabs | | 801824756 | MANUFACTURE(49035-665) , LABEL(49035-665) |

Revised: 12/2018

Walmart