EVERYMAN JACK SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion Prime Enterprises

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.

Everyman Jack SPF 50 Sheer Face Lotion

Active Ingredient

Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocryle 5%

Purpose

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.

Warnings

For external use only

Do not use on

damaged or broken skin

When using this product

Keep out of eyes. Rinse wih water to remove.

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 right away.

Directions

Apply liberally 15 minutes before sun exposure.

Reapply: After 80 minutes of swimming and sweating.

Immediately after towel drying.

At least every 2 hours.

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the 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. to 2 p.m.

Wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months: ask a doctor.

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butyrospermum Parkii (Shea) Butter, Cetyl Alcohol, Cetyl Phosphate, Ethylhexylglycerin, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, PEG-100 Stearate, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Propylene Glycol, Silica, Sodium Hydroxide, Stearyl Alcohol, Tetrasodium Glutamate Diacetate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

Ohter Information

Protect this product from excessive heat and direct sun.

Questions or Comments

877-875-5225, 9-5 PST weekdays.

Every Man Jack Face Shield Sun Protection Lotion SPF 50



EVERYMAN JACK SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0364

Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | |
|--|-------------------|------------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 49.9 mg in 1 mL | |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 29.94 mg in 1 mL | |

| OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W) | OCTISALATE | 49.9 mg in 1 mL |
|--|------------|-----------------|
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 99.8 mg in 1 mL |

| Inactive Ingredients | | |
|---|----------|--|
| Ingredient Name | Strength | |
| ALPHA-TO COPHEROL ACETATE (UNII: 9E8X80D2L0) | | |
| WATER (UNII: 059QF0KO0R) | | |
| PEG-100 STEARATE (UNII: YD01N1999R) | | |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) | | |
| PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R) | | |
| CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO) | | |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X) | | |
| SHEA BUTTER (UNII: K49 155WL9 Y) | | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| COCOA BUTTER (UNII: 5120 YT1CRR) | | |
| GLYCYRRHIZA GLABRA (UNII: 2788Z9758H) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | | |
| STEARYL ALCOHOL (UNII: 2KR8914H1Y) | | |
| SO DIUM HYDRO XIDE (UNII: 55X04QC32I) | | |
| PHENO XYETHANOL (UNII: HIE49 2ZZ3T) | | |
| CETYL PHO SPHATE (UNII: VT07D6X67O) | | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | | |
| TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL5014MY) | | |

| Product Characteristics | | |
|-------------------------|-------------------|--------------|
| Color | white (off white) | Score |
| Shape | | Size |
| Flavor | | Imprint Code |
| Contains | | |

| l | Packaging | | | |
|---|--------------------|--|-----------------------------|---------------------------|
| ı | # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| ı | 1 NDC:58443-0364-3 | 95 mL in 1 TUBE; Type 0: Not a Combination Product | 06/30/2020 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 06/30/2020 | |
| | | | |

Labeler - Prime Enterprises (101946028)

| Establishment | | | |
|-------------------|---------|---------------|--|
| Name | Address | ID/FEI | Business Operations |
| Prime Enterprises | | 10 19 46 0 28 | label(58443-0364), manufacture(58443-0364), analysis(58443-0364), pack(58443-0364) |

Revised: 10/2020 Prime Enterprises