

VASELINE TOTAL MOISTURE ALOE FRESH SPF 15- octisalate, avobenzone, ensulizole lotion

CONOPCO Inc. d/b/a Unilever

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.

Vaseline Total Moisture Aloe Fresh SPF 15

Active Ingredients

Avobenzone (2.0%), Ensulizole (1.5%), Octisalate (5.0%), Octocrylene (1.3%)

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 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 with 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 generously and evenly 15 minutes before sun exposure.
- children under 6 months of age: Ask a doctor
- reapply at least every two hours
- use a water resistant sunscreen if swimming or sweating

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 am - 2 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Water (Aqua), Glycerin, Stearic Acid, Glycol Stearate, PEG-100 Stearate, Dimethicone, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Dihydroxypropyltrimonium Chloride, Tocopheryl Acetate, Phenoxyethanol, Glyceryl Stearate, Potassium Stearate, Carbomer, Cetyl Alcohol, Caprylyl Glycol, Xanthan Gum, Fragrance (Parfum), Disodium EDTA, BHT, Stearamide AMP, Methylisothiazolinone.

1-800-457-7084

PDP 20.3 fl. oz.



Vaseline®
Total Moisture® Aloe Fresh SPF 15 lotion.
 Our light feeling formula absorbs quickly, infusing moisture at the top, core and deep down layers*, leaving skin hydrated.
 This lotion also contains broad spectrum UVA and UVB sunscreen for protected skin.
 *stratum corneum (multi-layer surface skin)

Drug Facts

Active ingredients	Purpose
Avobenzone (3.0%), Ensulizole (1.0%), Octisalate (5.0%)	Sunscreen

Uses • skin moisturization • helps prevent sunburn • if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early 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 with water to remove
Stop Use and ask a doctor if • rash occurs
Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right away.


Directions apply generously and evenly 15 minutes before sun exposure.


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 am – 2 pm.
 • Wear long-sleeved shirts, pants, hats, and sunglasses.


Inactive ingredients Water, Glycerin, Stearic Acid, Glycol Stearate, PEG-100 Stearate, Dimethicone, Aloe Barbadensis (Aloe Vera) Leaf Juice Powder, Dihydroxypropyltrimonium Chloride, Hydroxyethyl Urea, Glyceryl Stearate, Carbomer, Caprylyl Glycol, Cetyl Alcohol, Xanthan Gum, Fragrance, Stearamide AMP, Potassium Hydroxide, Phenoxyethanol, Disodium EDTA, Methylisothiazolinone.

Other Information
 • protect the product in this container from excessive heat and direct sun.

Questions or comments? Call toll free 1-800-457-7084


 3 05210 03684 0
DataLase Code Box


 Unilever
 © UNILEVER
 TRUMBULL, CT 06611
 VASELINE IS A UNILEVER TRADEMARK.
 83199682


 HDPE
 PLEASE RECYCLE

VASELINE TOTAL MOISTURE ALOE FRESH SPF 15

octisalate, avobenzone, ensulizole lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:64942-1190

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	15 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DIHYDROXYPROPYLTRIMONIUM CHLORIDE (UNII: V5RP514IX5)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARAMIDE AMP (UNII: U3K8640346)	
POTASSIUM STEARATE (UNII: 17V812XK50)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64942-1190-1	600 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2012	

Labeler - CONOPCO Inc. d/b/a Unilever (001375088)