

FOR MEN MACA ROOT ENERGETIC FACE PROTECTOR SPF 15- octisalate, avobenzone, octinoxate, and octocrylene lotion

Buth-Na-Bodhaige, Inc.,

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.

For Men Maca Root Energetic Face Protector SPF 15

Drug Facts

<i>Active Ingredients:</i>	<i>Purpose</i>
Avobenzone 3.0% (w/w),	Sunscreen
Octinoxate 2.9% (w/w),	Sunscreen
Octisalate 5.0% (w/w),	Sunscreen
Octocrylene 2.2% (w/w).	Sunscreen

Uses

- helps prevent sunburn.

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 liberally 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 sun especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses.
- reapply this product at least every 2 hours.
- use water resistant sunscreen if swimming or sweating.
- children under 6 months of age: ask a doctor.

Other information

- protect the product in this container from excessive heat and direct sun.

INACTIVE INGREDIENTS

Water, C12-15 Alkyl Benzoate, Glyceryl Stearate, Isononyl Isononanoate, Glycerin, Butylene Glycol, Sorbitol, Cetearyl Alcohol, Potassium Cetyl Phosphate, Phenoxyethanol, Caprylyl Glycol, Bertholletia Excelsa Seed Oil, Fragrance, Creatine, Xanthan Gum, Carbomer, Potassium Sorbate, Tetrasodium EDTA, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Hydrolyzed Lepidium Meyenii Root, 1,2-Hexanediol, Aloe Barbadensis Leaf Juice, BHT, Capryloyl Glycine, Citric Acid.

To report serious side effects associated with use of the product call 1-800-263-9746.

PRINCIPAL DISPLAY PANEL - 100 mL Tube Label

BROAD SPECTRUM SPF 15 SUNSCREEN

THE
BODY
SHOP®

**FOR MEN
MACA ROOT
ENERGETIC
FACE PROTECTOR
SPF 15**

**MOISTURISES and helps skin feel
smoother and protected, enriched
with Peruvian maca root.**

100 mL (3.3 US FL OZ)

BROAD SPECTRUM SPF 15 SUNSCREEN



FOR MEN
MACA ROOT
ENERGETIC
FACE PROTECTOR
SPF 15

MOISTURISES and helps skin feel smoother and protected, enriched with Peruvian maca root.

100 mL (3.3 US FL OZ)

827625

To report serious side effects associated with use of the product call 1-800-263-9746.

MADE IN UK FOR

© 2015 THE BODY SHOP INT'L PLC, LITTLEHAMPTON, BN17 6LS, UK

® registered trademark of

The Body Shop Int'l Plc.

www.thebodyshop.com

Drug Facts See Information Inside before using.

Active Ingredients:	Purpose
Avobenzone 3.0% (w/w),	Sunscreen
Octinoxate 2.9% (w/w),	Sunscreen
Octisalate 5.0% (w/w),	Sunscreen
Octocrylene 2.2% (w/w).	Sunscreen

Uses ■ helps prevent sunburn.

Warnings ■ For external use only.
Do not use ■ on damaged or broken skin

Directions: see Inside for directions
Inactive Ingredients: see Inside

To report serious side effects associated with use of the product call 1-800-263-9746.
MADE IN UK FOR © 2015 THE BODY SHOP INT'L PLC, LITTLEHAMPTON, BN17 6LS, UK.
® registered trademark of The Body Shop Int'l Plc.
www.thebodyshop.com
829493 SKU: 15298



Drug Facts (continued)

Warnings continued

■ 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

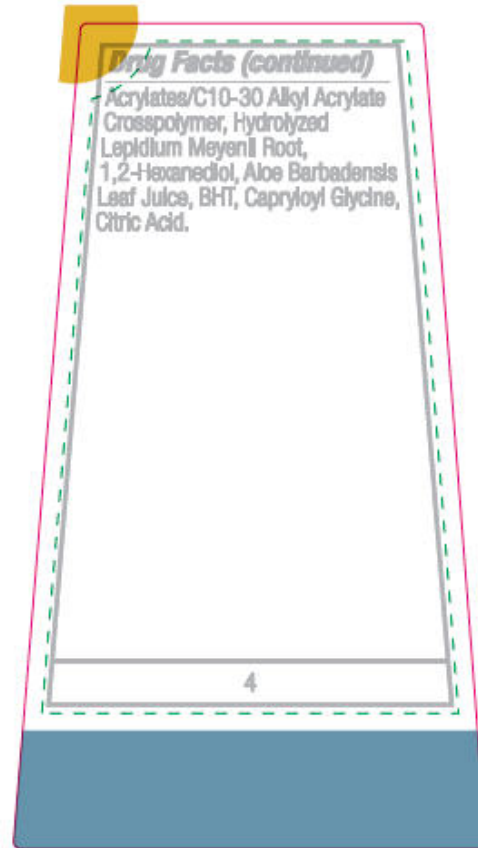
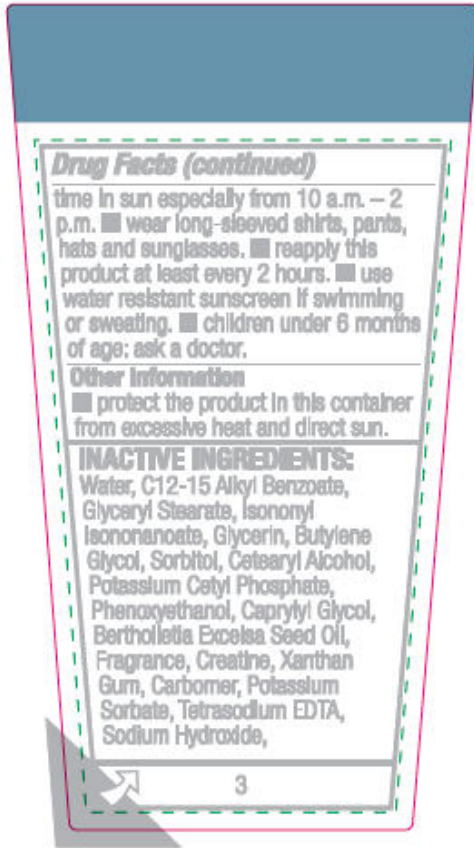
■ rash occurs.

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

Directions ■ Apply liberally 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



FOR MEN MACA ROOT ENERGETIC FACE PROTECTOR SPF 15

octisalate, avobenzone, octinoxate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57691-298
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 mL
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.029 g in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.022 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

Alkyl (C12-15) Benzoate (UNII: A9EJ3J61HQ)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
Isononyl Isononanoate (UNII: S4V5BS6GCX)
Glycerin (UNII: PDC6A3C0OX)
Butylene Glycol (UNII: 3XUS85K0RA)
Sorbitol (UNII: 506T60A25R)
Cetostearyl Alcohol (UNII: 2DMT128M1S)
Potassium Cetyl Phosphate (UNII: 03KCY6P7UT)
Phenoxyethanol (UNII: HIE492ZZ3T)
Caprylyl Glycol (UNII: 00YIU5438U)
Brazil Nut Oil (UNII: 0G89T29HO6)
Creatine (UNII: MU72812GK0)
Xanthan Gum (UNII: TTV12P4NEE)
Potassium Sorbate (UNII: 1VPU26JZZ4)
EDETATE SODIUM (UNII: MP1J8420LU)
Sodium Hydroxide (UNII: 55X04QC32I)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)
HYDROLYSED LEPIDIUM MEYENII ROOT (ENZYMATIC) (UNII: P2799BF6GS)
1,2-Hexanediol (UNII: TR046Y3K1G)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
Capryloyl Glycine (UNII: 8TY5YO42NJ)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57691-298-10	100 mL in 1 TUBE; Type 0: Not a Combination Product	03/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/14/2016	

Labeler - Buth-Na-Bodhaige, Inc., (791071279)