

OUTBACK SERIES 2-IN-1 SUNSCREEN- octyl methoxycinnamate, avobenzone and zinc oxide cream

Elmore Oil Company 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 ingredient

Octyl Methoxycinnamate - 7.5%

Avobenzone - 1.3%

Zinc Oxide - 9.5%

Purpose

Sunscreen 30+

Indication and Usage

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.

Dosage and Administration

Apply liberally 15 minutes before sun exposure reapply: after 40 minutes of swimming or sweating immediately after towel drying at least every 2 hours.

Warnings

For external use only. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if a rash occurs. Keep out of reach of children. If product is swallowed, get medical help or contact the Poison Control Center right away.

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 of 15 or higher and other sun protection measures including: limit time in the sun, especially between 10 a.m – 2 p.m. wear long-sleeve shirts, pants, hats and sunglasses. children under 6 months: Ask a doctor.

Inactive Ingredients

Actilastin 1000, Melaleuca Alternifolia, Eucalyptus Polybractea, Citronella, Leptospermum Petersonii, Vanilla

Keep out of Reach of Children

Keep Out of Reach of Children

Product Label

OUTBACK

2-in-1 Protection

Insect repellent & protective sunscreen

www.TheOutbackSeries.com

SPF **30+**
UVA-UVB BROAD SPECTRUM



2-in-1



Made In Australia

UVA-UVB Broad Spectrum
Sunscreen - SPF:30+
75ml (2.5 fl oz.)

Drug Facts

Active Ingredients

Octyl Methoxycinnamate 7.5%
Avobenzone 1.3%
Zinc Oxide 9.5%

Purpose
Sunscreen

Uses

- helps prevent sunburn
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Warnings

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Directions

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- reapply: • after 40 minutes of swimming or 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 of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially between 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses.
 - children under 6 months: Ask a doctor

Inactive Ingredients

Actinastin 1000, Melaleuca Alternifolia, Eucalyptus Polytrachtes, Citronella, Leptospermum Petersonii, Vanilla

Other Information

- Protect this product from excessive heat and direct sun.

Questions or Comments? Call 1-800-215-8739

1-800-215-8739

Pain Away, LLC
200 Moore Dr.
Nicholasville, KY 40356





OUTBACK SERIES 2-IN-1 SUNSCREEN

octyl methoxycinnamate, avobenzone and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:439 79 -446
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	13 mg in 1 mL
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EUCALYPTUS POLYBRACTEA LEAF OIL (UNII: J1XGA6WROO)	
LEPTOSPERMUM PETERSONII LEAF OIL (UNII: N37UWG52T3)	
CITRONELLA OIL (UNII: QYO8Q067D0)	
TEA TREE OIL (UNII: VIF565UC2G)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43979-446-01	3 mL in 1 POUCH		
2	NDC:43979-446-03	75 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/01/2013	

Labeler - Elmore Oil Company Pty Ltd (755881968)

Establishment

Name	Address	ID/FEI	Business Operations
Elmore Oil Company Pty Ltd		755881968	manufacture(43979-446) , pack(43979-446) , label(43979-446)

Revised: 6/2013

Elmore Oil Company Pty Ltd