

**OUTBACK 2 IN 1 PROTECTION- octinoxate, avobenzone and zinc oxide cream
Ultra Mix (Aust) 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.

Outback 2 in 1 Protection

Active Ingredients

OCTINOXATE : 7.5 % AVOBENZONE : 1.3% ZINC OXIDE :9.5%

Inactives

TEA TREE OIL

EUCALYPTUS POLYBRACTEA LEAF OIL

CITRONELLA OIL

LEPTOSPERMUM PETERSONII LEAF OIL

VANILLA

ACTILASTIN 1000

Purpose

Sunscreen, helps prevent sunburn.

Directions of Usage

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 immediately.

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

Product Label

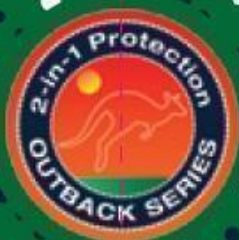
OUTBACK

2-in-1 Protection

Insect repellent & protective sunscreen

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

2-in-1



Made in Australia

Drug Facts
Active Ingredients
 Octyl Methoxycinnamate 7.5%
 Avobenzone 1.3%
 Zinc Oxide 9.5%
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
 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 immediately.

Directions
 • Apply liberally 15 minutes before sun exposure
 • 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
 Actilastin 1000, Melaleuca Alternifolia, Eucalyptus Polybractea, Citronella, Leptospermum Petersonii, Vanilla.

Other Information
 • Protect this product from excessive heat and direct sun.

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

www.TheOutbackSeries.com

1-800-215-8739

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

Ultra Mix (Aust) Pty Ltd
6 McArthur St
West Footscray
Victoria, Australia



OUTBACK 2 IN 1 PROTECTION

octinoxate, avobenzone and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69594-005
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 CATION - UNII:13S1S8SF37)	ZINC CATION	95 mg in 1 mL

Inactive Ingredients

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

Product Characteristics

Color		Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69594-005-01	75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/16/2015	

Labeler - Ultra Mix (Aust) Pty Ltd (752254649)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Mix (Aust) Pty Ltd		752254649	manufacture(69594-005) , label(69594-005)

Revised: 2/2015

Ultra Mix (Aust) Pty Ltd