

**MOISTURISING SUNSCREEN SPF 30- homosalate, octisalate, octinoxate, octocrylene cream  
Eshu 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.*

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**Moisturizing Sunscreen SPF 30+**

Active ingredients	Purpose
Homosalate 8%	Sunscreen
Octisalate 4%	Sunscreen
Octinoxate 3%	Sunscreen
Octocrylene 2%	Sunscreen

Uses

- Helps prevent sunburn
- higher SPF gives more sunburn protection
- provides high protection against sunburn
- for skin highly sensitive to sunburn

Keep out of reach of children

-Stop use and ask a doctor if rash or irritation occurs.

-Sun Alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce risk of skin aging, skin cancer, and other harmful effects of the sun

- Does not provide protection for already burnt skin
- every case of sunburn damages the skin permanently
- does not provide 100% protection against UV radiation
- store in a cool dry place

-keep carton. It contains important information  
warnings

For external use only

When using this product keep out of eyes. rinse with water to remove

If swallowed, get medical help or call a poison control center right away

Directions

- apply liberally and generously onto clean, dry skin and rub in evenly 20 minutes prior to sun exposure
- apply enough to give a visible layer before rubbing in .
- re-apply as needed every 1-2 hours, or after towel drying, swimming, or perspiring.

-Children under 6 years of age: ask a doctor.

### Inactive ingredients

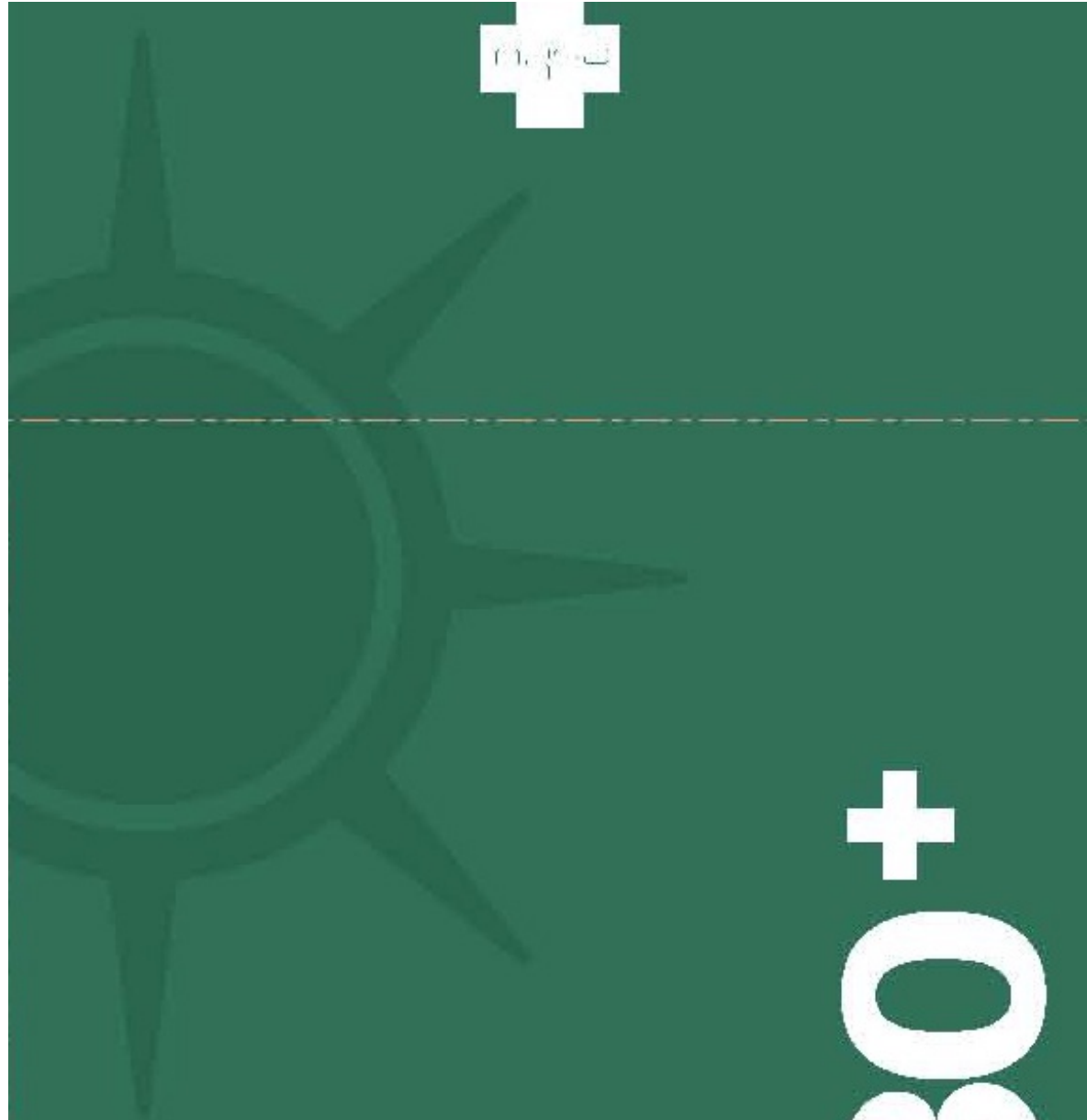
Allantoin, Ammonium Acryloyldimethicone/VP copolymer, Caprylyl Glycol, Cetareth-20, Cetearyl Alcohol, Cetyl Dimethicone, Cyclomethicone, Disodium EDTA, Ethyl Linoleate, Fragrance, Isostearyl Neopentanoate, Lactic Acid, Glycerin, Peg-40 Stearate, Polypropylene, Xanthan gum, Octanohydroxamic acid, Oleyl Alcohol, Panthenol, Panthenyl Triacetate, Pentylene Glycol, Serine, Silica, Sodium chloride, Sodium Lactate, Sorbitol, Tocopherol, Triaccontanyl PVP, Urea, water.

<p><b>Drug Facts</b></p> <table><thead><tr><th><b>Active Ingredients</b></th><th><b>Purpose</b></th></tr></thead><tbody><tr><td>Homosalate 8% } Octisalate 4% } Octinoxate 3% } Octocrylene 2% }</td><td>Sunscreen</td></tr></tbody></table> <p><b>Uses</b></p> <ul style="list-style-type: none"><li>• helps prevent sunburn</li><li>• higher SPF gives gives more sunburn protection</li><li>• provides high protection against sunburn</li><li>• for skin highly sensitive to sunburn</li></ul> <p><b>Warnings</b></p> <p><b>For external use only.</b> <b>When using this product keep out of eyes. Rinse with water to remove.</b> <b>Stop use and ask a doctor if rash or irritation develops and lasts.</b> <b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"><li>• apply liberally and generously onto clean, dry skin and rub in evenly 20 minutes prior to sun exposure.</li><li>• apply enough to give a visible layer before rubbing in.</li><li>• re-apply as needed every 1-2 hours, or after towel drying, swimming or perspiring.</li><li>• children under 6 months of age: ask a doctor</li></ul> <p><b>Other Information</b></p> <ul style="list-style-type: none"><li>• sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.</li><li>• does not provide protection for already burnt skin</li><li>• every case of sunburn damages the skin permanently</li><li>• does not provide 100% protection against UV radiation</li><li>• store in a cool, dry place</li><li>• keep carton. It contains important information.</li></ul> <p><b>Inactive Ingredients:</b> Allantoin, Ammonium Acryloyldimethylsulfonate / VP Copolymer, Caprylyl Glycol, Cetareth-20, Cetearyl Alcohol, Cetyl Dimethicone, Cyclomethicone, Disodium EDTA, Ethyl Linoleate, Fragrance, Isostearyl Neopentanoate, Lactic Acid, Glycerin, Peg-40 Stearate, Polypropylene, Xanthan Gum, Octanohydroxamic acid, Oleyl Alcohol, Panthenol, Panthenyl Triacetate, Pentylene Glycol, Serine, Silica, Sodium Chloride, Sodium Lactate, Sorbitol, Tocopherol, Triaccontanyl PVP, Urea, Water.</p> <p><b>Questions or comments?</b> Toll Free 1-855-229-ESHU Monday through Friday, 9am-5pm, <a href="http://www.eshu.com.au">www.eshu.com.au</a></p>	<b>Active Ingredients</b>	<b>Purpose</b>	Homosalate 8% } Octisalate 4% } Octinoxate 3% } Octocrylene 2% }	Sunscreen	<p><b>what's in it:</b> eshu moisturising sunscreen SPF30+ contains broad spectrum sunscreen filters to help protect the skin and Vitamin E to help moisturise it. The scent of Eucalyptus, Citrus and Mint leaves you feeling refreshed.</p> <p><b>How to use it:</b> Please see the back of our box. Remember to always take care in the sun. After all, despite what you may think, your skin is your biggest organ so it deserves the best protection.</p> <p>Manufactured for eshu Pty. Ltd Ground Floor Suite 3,24 Albert Rd. South Melbourne VIC. Australia 3205</p>
<b>Active Ingredients</b>	<b>Purpose</b>				
Homosalate 8% } Octisalate 4% } Octinoxate 3% } Octocrylene 2% }	Sunscreen				

Moisturizing Sunscreen SPF 30+

100 mL/3.4 oz





moisturising  
sunscreen  
SPF **30+**

100 mL

oil-free

3.4 oz

ESTIO®

**MOISTURISING SUNSCREEN SPF 30**

homosalate, octisalate, octinoxate, octocrylene cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42315-672
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	8 mL in 100 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	4 mL in 100 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYL LINOLEATE</b> (UNII: MJ2YTT4J8M)	
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>OLEYL ALCOHOL</b> (UNII: 172F2WN8DV)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>SERINE</b> (UNII: 452VLY9402)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42315-672-02	1 in 1 BOX		
1	NDC:42315-672-01	100 mL in 1 BOTTLE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/17/2011	

**Labeler** - Eshu Pty Ltd (753614812)

**Registrant** - Baxter Laboratories Pty. Ltd. (740537709)

## Establishment

Name	Address	ID/FEI	Business Operations
Baxter Laboratories Pty. Ltd.		740537709	manufacture

Revised: 1/2012

Eshu Pty Ltd