

SUNSCREEN SPF 30- zinc oxide cream
Hamilton Therapeutics

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.

Sunscreen SPF 30

Active ingredient Purpose

Zinc Oxide 15% 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.

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

- **Stop use and ask a doctor** if rash occurs.

Warnings

- **For external use only**
- **When using this product** keep out of eyes.
- Rinse with water to remove.
- Do not use on damaged or broken skin.

Directions

- For full protection, apply liberally 15 minutes before sun exposure.
- Reapply: • After 40 minutes of swimming or sweating • immediately after towel drying
- at least every 2 hours.
- For children under 6 months: Ask a doctor. • Sun Protection Measures: To decrease risk of exposure, regularly use a Broad Spectrum Sunscreen with an SPF of 15 or higher.
- Limit time in the sun, especially from 10AM-2PM.
- Wear long-sleeved shirts, pants, hats and sunglasses.

Inactive ingredients Water, Caprylyl Caprylate/Caprates, Coconut Alkanes, Potassium Cetyl Phosphate, Cetearyl Alcohol, Glycerin, Bisabolol, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Limon (Lemon) Peel Extract, Salvia Officinalis (Sage) Leaf Extract, Thymus Vulgaris (Thyme) Flower/Leaf Extract, Coco-Caprylate/Caprates, Glyceryl Stearate, Xanthan Gum, Polyhydroxystearic Acid, Glyceryl Distearate, Stearic Acid, Potassium Stearate, Octyldodecanol, Ethylhexyl Neopentanoate,

Dimethicone, Phenethyl Alcohol, Sodium Dehydroacetate, Caprylhydroxamic Acid.

SPF 30 Sunscreen

3.3FL OZ / 98mL

HAMILTON BABIES SANTA MONICA

Lively Levi

SPF 30

SUNSCREEN

All things new...

PHENOXYETHANOL FREE

3.3 FL OZ / 98mL

*Sulfate Free • Phthalate Free
Gluten Free • Paraben Free*

Drug Facts	
Active ingredient	Purpose
Zinc Oxide 15%	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. • When using this product keep out of eyes. • Rinse with water to remove. • Do not use on damaged or broken skin. • 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 • For full protection, apply liberally 15 minutes before sun exposure. • Reapply: • After 40 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours. • For children under 6 months: Ask a doctor. • Sun Protection Measures: To decrease risk of exposure, regularly use a Broad Spectrum Sunscreen with an SPF of 15 or higher. • Limit time in the sun, especially from 10AM-2PM. • Wear long-sleeved shirts, pants, hats and sunglasses.	
Other information • Protect this product from direct sunlight and excessive heat.	
Inactive ingredients Water, Caprylyl Caprylate/Caprate, Coconut Alkanes, Potassium Cetyl Phosphate, Cetearyl Alcohol, Glycerin, Bisabolol, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Citrus Limon (Lemon) Peel Extract, Salvia Officinalis (Sage) Leaf Extract, Thymus Vulgaris (Thyme) Flower/Leaf Extract, Coco-Caprylate/Caprate, Glyceryl Stearate, Xanthan Gum, Polyhydroxystearic Acid, Glyceryl Distearate, Stearic Acid, Potassium Stearate, Octyldodecanol, Ethylhexyl Neopentanoate, Dimethicone, Phenethyl Alcohol, Sodium Dehydroacetate, Caprylhydroxamic Acid.	

Distributed by:
Hamilton Therapeutics
Santa Monica, CA 90404
(424) 317-5555
Made in U.S.A.

8 52020 08011 7

www.HamiltonTherapeutics.com

SUNSCREEN SPF 30

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72381-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	15 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CITRUS AURANTIUM FLOWER (UNII: O730ZX2Z83)	
ORANGE PEEL (UNII: T19T76XD44)	
LEMON PEEL (UNII: 72O054U628)	
SAGE (UNII: 065C5D077J)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POTASSIUM STEARATE (UNII: 17V812XK50)	

OCTYLDODECANOL (UNII: 461N1O614Y)
DIMETHICONE (UNII: 92RU3N3Y1O)
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
CAPRYLYL CAPRYLATE/CAPRATE (UNII: 22MCG4RSMR)
COCONUT ALKANES (UNII: 1E5KJY107T)
GLYCERYL DISTEARATE (UNII: 73071MW2KM)
WATER (UNII: 059QF0KO0R)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
LEVOMENOL (UNII: 24WE03BX2T)
GLYCERIN (UNII: PDC6A3C0OX)
CHAMOMILE (UNII: FGL3685T2X)
THYME (UNII: CW657OBU4N)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)
STEARIC ACID (UNII: 4ELV7Z65AP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72381-102-01	98 mL in 1 TUBE; Type 0: Not a Combination Product	06/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/15/2018	

Labeler - Hamilton Therapeutics (099419360)