

BABY BUM SPF50 MINERAL SUNSCREEN- zinc oxide cream
Sun Bum, LLC

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.

Baby Bum SPF50 Mineral Sunscreen Lotion

Drug Facts

Active Ingredients

Zinc oxide 20%

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.

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 swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- apply liberally 15 minutes before sun exposure.
- reapply: after 80 minutes of swimming or sweating.
- immediately after towel drying.

- at least every 2 hours.
- children under 6 months of age: ask a doctor.
- **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 of 15 or higher and other sun protection measures, including:
- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses.

Other Information

- protect this product from excessive heat and direct sun.
- keep outer card for complete directions and warnings

Inactive ingredients

water, cocos nucifera (coconut) oil, butyloctyl salicylate, diheptyl succinate, methyl dihydroabietate, butyrospermum parkii (shea butter), capryloyl glycerin/sebacic acid copolymer, sodium stearoyl glutamate, cetearyl alcohol, theobroma cacao (cocoa) seed butter, sodium hyaluronate, bisabolol, tocopherol, coco-glucoside, microcrystalline cellulose, cellulose gum, cetyl alcohol, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, polyhydroxystearic acid, sodium gluconate, phenoxyethanol, ethylhexylglycerin, citric acid

Questions?

call 1 877-978-6286

Package Labeling:



baby BUM

Mineral 50

Mineral Sunscreen Lotion
Broad Spectrum SPF 50
Water Resistant (80 Minutes)

Plant-Based Ingredients

Non-Nano • Vegan • Hypoallergenic
Pediatrician Tested

Fragrance Free

3 FL OZ / 88 ml



Mineral SPF 50 Lotion

● Gluten Free ● Cruelty Free ● Paraben Free ● Phthalate Free

Drug Facts	
<i>Active ingredient</i>	<i>Purpose</i>
Zinc oxide 20%	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	
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 swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • apply liberally 15 minutes before sun exposure • reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • children under 6 months of age: ask a doctor • 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 the sun, especially from 10 a.m.- 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses	
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Questions? 1-877-978-6286	



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Package Labeling:69039-255-01



Mineral 50

Moisturizing Sunscreen Lotion
Broad Spectrum SPF 50
Water Resistant (80 Minutes)

Fragrance Free

Sample Only / Not For Resale
0.5 FL OZ / 15 mL

Xela Pack®

Trust The Bum

Bend Here
And Tear

Drug Facts

Active ingredient

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Sunscreen

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Stop use and ask a doctor if rash occurs

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Directions

- apply liberally 15 minutes before sun exposure
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- **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 10am-2pm • wear long-sleeved shirts, pants, hats and sunglasses

Other information protect this product from excessive heat and direct sun

Questions? Call 1 (877) 978-6286

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BABY BUM SPF50 MINERAL SUNSCREEN

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCONUT OIL (UNII: Q9L0O73W7L)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIHEPTYL SUCCINATE (UNII: 057N7SS26Y)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S) (UNII: N7YC58165T)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCOA BUTTER (UNII: 512OYT1CRR)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LEVOMENOL (UNII: 24WE03BX2T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCO GLUCOSIDE (UNII: ICS790225B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35J00J)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69039-255-00	88 mL in 1 TUBE; Type 0: Not a Combination Product	10/11/2017	
2	NDC:69039-255-01	15 mL in 1 PACKET; Type 0: Not a Combination Product	03/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/11/2017	

Labeler - Sun Bum, LLC (028642574)

Revised: 2/2022

Sun Bum, LLC