

BABYGANICS SPF 50- octinoxate, octisalate, and zinc spray
Autumn Harp, Inc.

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.

Drug Facts

Active Ingredients

Active Ingredients	Purpose
Octinoxate 7.5%, Octisalate 5.0%, Zinc Oxide 11.2%	Sunscreen

Uses

Uses

helps prevent sunburn

if used as directed with other sun protection measures (see Directions), decrease the risk of skin cancer and early skin aging caused by the sun

Warnings

Warnings

For external use only

Do not use

Do not use on damaged or broken skin

When using this product

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

Stop use and ask a doctor

Stop use and ask a doctor if rash occurs

Keep out of reach of children

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

Directions

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

Sun Protection measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk of skin cancer and early skin aging. To decrease this risk sunscreen with Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

limit time in the sun, especially from 10 am - 2 pm.

wear long-sleeved shirts, pants, hats, and sunglasses

Other Information

Other information

protect from excessive heat and direct sun

Inactive ingredients

Inactive Ingredients: Water, Glycerin, Caprylic/Capric Triglyceride, Aloe Barbadensis Leaf Juice, VP/hexadecene copolymer, Cetearyl Glucoside, Phenethyl Alcohol, Glyceryl Caprylate, Polyacrylate Crosspolymer-6, Cetearyl Alcohol, Citric Acid.

Label



WHITE



WHITE

stokecreative

02/08/2012 DATE
KAS DIRECT CLIENT
BG COVER UP BABY PROJECT
ILLUSTRATOR CSS SOFTWARE
BG_Sunscreen(babyganics) TITLE

PANTONE® 377 C
 PANTONE® 116 C
 PANTONE® 158 C
 PANTONE® 217 C
 PANTONE® 258 C

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BABYGANICS SPF 50

octinoxate, octisalate, and zinc spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0235
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	112 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0235-1	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/23/2012	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0235)

Revised: 11/2018

Autumn Harp, Inc.