

WALGREENS BABY SPF50- titanium dioxide and zinc oxide lotion

Walgreen Company

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.

WAG Sun Baby Lotion SPF50 6oz

1491-23(V) Rev 01

Walgreen Baby SPF 50 Lotion

Active Ingredients

Titanium Oxide 3.30%, Zinc Oxide 4.2%

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 right away.

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
- **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
- children under 6 months: Ask a doctor

Inactive Ingredients

Deionized Water, Caprylic/Capric Triglycerides, Tridecyl Neopentanoate, Sorbitol, Cetyl PEG/PPG 10/1 Dimethicone, Butyl Octyl Salicylate, Glycerin, Octyldodecyl Citrate Copolymer, C28-52 Olefin/Undecylenic Acid Copolymer, PEG 8, Dimethicone, Aloe Barbadensis Leaf Juice, Ethylhexyl Methoxycrylene, Tocopherol Acetate, Lauryl PEG-8 Dimethicone, Caprylyl Glycol, Sodium Chloride, Phenoxyethanol, Sodium Citrate

Other Information

- for use on skin only. Avoid contact with fabric
- protect this product from excessive heat and direct sun

Questions or comments?

www.walgreens.com or call toll free 1-800-XX-XXXX

PRINCIPAL DISPLAY PANEL

Walgreens

50

Baby

Broad spectrum SPF 50

Sunscreen UVA/UVB

HYPOALLERGENIC

OXYBENZONE FREE

TEAR FREE

6 FL OZ (176 mL)

Drug Facts

Active Ingredient
Titanium Dioxide 3.1%, Zinc Oxide 4% } **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 product is swallowed, get medical help or contact a Poison Control Center right away. May stain some fabrics

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
- Sun Protection Measures
- Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use 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-sleeved shirts, pants, hats and sunglasses
 - Children under 6 months of age: ask a doctor

Inactive Ingredients:
Water, Caprylic/Capric Triglycerides, Tridecyl Neopentanoate, Butyl Octyl Salicylate, Octyldecyl Citrate Copolymer, Cetyl PEG/PPG 10/1 Dimethicone, C20-52 Olefin/Undecylenic Acid Copolymer, PEG-8, Dimethicone, Glycerin, Aloe Barbadosum Leaf Juice, Ethylhexyl Methoxycrylate, Tocopheryl Acetate, Lauryl PEG-8 Dimethicone, Caprylyl Glycol, Sodium Chloride, Phenoxyethanol, Sodium Citrate

Other Information

- protect this product from excessive heat and direct sun

Questions or Comments?
1-800-925-4733

DEVELOPED BY: WALGREEN CO.
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Walgreens

NEW

**50
Baby**

BROAD SPECTRUM SPF 50
SUNSCREEN UVA/UVB

HYPOALLERGENIC

OXYBENZONE FREE

TEAR FREE

- Water resistant (80 minutes)

6 FL OZ (176 mL)



WALGREENS BABY SPF50

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9936
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	3.1 mg in 100 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	4 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TRIDECYL NEOPENTANOATE (UNII: 3Z8H1DA7J5)	
SORBITOL (UNII: 506T60A25R)	

CETYL PEG/PPG-10/1 DIMETHICONE (HLB 3) (UNII: G300307ZXP)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
GLYCERIN (UNII: PDC6A3C0OX)
POLYOXYL 8 STEARATE (UNII: 2P9L47VI5E)
DIMETHICONE (UNII: 92RU3N3Y1O)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM CITRATE (UNII: 1Q73Q2JULR)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9936-26	178 mg in 1 BOTTLE; Type 0: Not a Combination Product	11/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	11/15/2017	

Labeler - Walgreen Company (008965063)

Registrant - Walgreen Company (008965063)

Revised: 8/2017

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