

LEADER KIDS SUNSCREEN SPF 50- titanium dioxide, zinc oxide lotion

Cardinal Health

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.

Leader Kid's Sunscreen SPF 50 Lotion

Active Ingredients

Titanium Dioxide 4.5%, Zinc Oxide 6.5%

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 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.

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: 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

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive Ingredients

water, caprylic/capric triglyceride, isohexadecane, butyloctyl salicylate, octyldodecyl citrate crosspolymer, cetyl PEG/PPG-10/1 dimethicone, lauryl PEG-8 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sodium chloride, ethylhexyl methoxycrylene, dimethicone, caprylyl glycol, PEG-8, silica, triethoxycaprylylsilane, glycerin, sodium citrate, tocopheryl acetate, benzyl alcohol, benzoic acid, sorbic acid.

Label



We care about kid's delicate skin. **LEADER™ Kid's Sunscreen Lotion** delivers broad spectrum UVA/UVB sun protection with this tear-free formula. Water resistant up to 80 minutes for protection you can trust.

Drug Facts	
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Questions or comments? Call toll free 1-800-527-7731	

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**No parabens separately added to preserve this product.
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LEADER KIDS SUNSCREEN SPF 50

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0545
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	65 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	45 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
1,5-PENTANEDIOL (UNII: 07UXZ0SCST)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0545-1	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/11/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/11/2019	

Labeler - Cardinal Health (063997360)