

# **CVS HEALTH KIDS AND BABY 50 MINERAL-BASED- octisalate, zinc oxide lotion CVS PHARMACY**

*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.*

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## **CVS HEALTH KIDS AND BABY 50 MINERAL-BASED LOTION**

### **Active ingredients**

Octisalate 5.0%, Zinc Oxide 14.5%

### **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 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
- 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

### **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, C12-15 Alkyl Benzoate, Neopentyl Glycol Diheptanoate, Propylene Glycol, Tridecyl Salicylate, Cyclopentasiloxane, Cetyl PEG/PPG-10/1 Dimethicone, PEG-12 Dimethicone Crosspolymer, Triethoxycaprylylsilane, Aloe Barbadensis Leaf Juice, Ethylhexyl Palmitate, Caprylyl Glycol, Phexoethanol, Hexylene Glycol, Sodium Chloride.

### **Label**

**CVS Health™ Baby Mineral-Based Lotion SPF 50** provides light coverage with broad-spectrum protection. Its mineral-based formula won't irritate eyes and absorbs quickly. Water-resistant, it provides protection in and out of the water for up to 80 minutes.

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Octisalate 5.0% Zinc Oxide 14.5%	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b>	
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.	
<b>Directions</b>	
• 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	
• <b>Sun Protection Measures.</b> 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	
<b>Other information</b>	
• protect this product from excessive heat and direct sun	
• may stain or damage some fabrics, materials or surfaces	
<b>Inactive ingredients</b>	
water, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, propylene glycol, triethyl salicylate, cyclopentasiloxane, cetyl PEG/PPG-10/1 dimethicone, PEG-12 dimethicone crosspolymer, triethoxycaprylylsilane, aloe barbadensis leaf juice, ethylhexyl palmitate, benzyl alcohol, benzoic acid, sorbic acid, sodium chloride	

#224599



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**CVS Health™**



**baby**

**50**

**MINERAL-BASED LOTION**

**BROAD SPECTRUM SPF 50 SUNSCREEN**

UVA/UVB protection

- Water resistant (80 minutes)
- Tear free & fragrance free
- Pediatrician tested
- Oxybenzone & octinoxate free



RECOMMENDED AS AN EFFECTIVE BROAD SPECTRUM SUNSCREEN



COMPARE TO COPPERTONE® WATERBABIES® PURE & SIMPLE LOTION\*

6 FL OZ (177 mL)

**CVS Health™ Children's Mineral-Based Lotion**  
**SPF 50** provides light coverage with broad-spectrum protection. Its mineral-based formula won't irritate eyes and absorbs quickly. Water-resistant, it provides protection in and out of the water for up to 80 minutes.

**Drug Facts**

Active Ingredients	Purpose
Octisalate 5.0%	Sunscreen
Zinc Oxide 14.5%	

**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

• 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
- may stain or damage some fabrics, materials or surfaces

**Inactive ingredients**

water, C12-15 alkyl benzoate, neopentyl glycol diheptanoate, propylene glycol, tridecyl salicylate, cyclopentasiloxane, cetyl PEG/PPG-10/1 dimethicone, PEG-12 dimethicone crosspolymer, triethoxycaprylylsilane, aloe barbadensis leaf juice, ethylhexyl palmitate, benzyl alcohol, benzoic acid, sorbic acid, sodium chloride

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#224595



**children's**

**50**

**MINERAL-BASED LOTION**

**BROAD SPECTRUM SPF 80 SUNSCREEN**  
**UVA/UVB protection**

- Water resistant (80 minutes)
- Won't irritate eyes
- Dermatologist tested
- Oxybenzone & octinoxate free



COMPARE TO COPPERTONE® KIDS SPF LOTION\*

6 FL OZ (177 mL)




**baby**  
**50**  
**MINERAL-BASED LOTION**

**BROAD SPECTRUM SPF 50 SUNSCREEN**  
 UVA/UVB protection

- Water resistant (80 minutes)
- Tear free & fragrance free
- Pediatrician tested
- Oxybenzone & octinoxate free



COMPARE TO COPPERTONE®  
 WATERBABIES® PURE & SIMPLE LOTION\*


**8.0 FL OZ (237 mL)**

**CVS Health™ Mineral-Based Baby Lotion SPF 50** is a broad-spectrum, tear-free sunscreen. Its hypoallergenic formula contains no oils, fragrances or dyes, ideal for baby's delicate skin. Water-resistant formula provides protection in and out of the water for up to 80 minutes.


Drug Facts	
Active Ingredients	Purpose
Octisalate 5.0% Zinc Oxide 14.5%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• reapply:               <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• children under 6 months of age: ask a doctor</li> <li>• 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:               <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun</li> <li>• may stain or damage some fabrics, materials or surfaces</li> </ul>	
<b>Inactive ingredients</b>	
water, G12-15 alkyl benzoate, neopentyl glycol diheptanoate, propylene glycol, trisetyl salicylate, cyclopentasiloxane, cetyl PEG/PPG-10/1 dimethicone, PEG-12 dimethicone crosspolymer, triethoxycaprylylsilane, aloe barbadensis leaf juice, ethylhexyl palmitate, benzyl alcohol, benzoic acid, sorbic acid, sodium chloride	

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## CVS HEALTH KIDS AND BABY 50 MINERAL-BASED

octisalate, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-041
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	145 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKWBC543X)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5)</b> (UNII: 035JKJ76MT)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>CYCLOMETHICONE 4</b> (UNII: CZ227117JE)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-041-71	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/02/2019	
2	NDC:51316-041-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/13/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/13/2018	

**Labeler** - CVS PHARMACY (062312574)

Revised: 4/2023

CVS PHARMACY