ATTITUDE MINERAL SUNSCREEN LITTLE ONES - FRAGRANCE FREE- zinc oxide cream Bio Spectra

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.

ATTITUDE® DRUG FACTS

Active ingredient

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. If rash occurs, stop use and ask a octor.

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

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:
 - At least every 2 hours
 - After 40 minutes of swimming or sweathing
 - Immediately after towel drying
- 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 10am–2pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses

- Ask a doctor for use on children under 6 months of age.

Inactive ingredients

Aqua, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate.

Other Information

Store at temperatures below 90oF.

PRINCIPAL DISPLAY PANEL - 75 g Tube Label

BIO SPECTRA ATTITUDE®

little ones

30

SPF

100% MINERAL SUNSCREEN fragrance-free • hypoallergenic BROAD SPECTRUM (UVA/UVB), NON NANO DERMATOLOGICALLY TESTED

• EWG VERIFIED • FOR YOUR HEALTH • EWG.ORG $^{\text{TM}}$

WORRY-FREE

• INGREDIENTS •

NPN 80047088 • 75 g / 2.6 OZ.

DRUG FACTS / RENSEIGNEMENTS

Active ingredient / Ingrédient médicinal

Purpose / Utilisation

Zinc oxide / Oxyde de zinc (20%)......Sunscreen / Crème solaire

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. Utilisation : ■ Aide à prévenir les coups de soleil ■ Si utilisé selon le mode d'emploi et avec d'autres mesures de protection (voir Mode d'emploi), diminue les risques de cancer de la peau et de vieillissement prématuré de la peau.

Warnings / Attention :

75001 / T:+33

For external use only, / Pour usage externe seulement,

Do not use on damaged or broken skin. If rash occurs, stop use and ask a doctor. Ne pas utiliser sur la peau endommagée ou présentant des lésions. En présence d'une éruption cutanée, cesser l'utilisation et consulter un professionnel de la santé.

When using this product keep out of eyes. Rinse with water to remove. Éviter tout contact avec les yeux. Rincer à l'eau le cas échéant.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. / Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison.

Directions: ■ Apply liberally 15 minutes before sun exposure ■ Reapply ■ At least every 2 hours After 40 minutes of swimming or sweating Immediately after towel drying Ask a doctor for use on children under 6 months of age. 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 10am-2pm ■ Wear long-sleeved shirts, pants, hats, and sunglasses Mode d'emploi : ■ Appliquer généreusement et uniformément 15 minutes avant l'exposition au soleil. ■ Appliquer de nouveau ■ au moins toutes les 2 heures. ■ Utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration. ■ Pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé.

Mesures de protection contre le soleil : Passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. ■ Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un F.P.S. à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que : ■ limiter le temps passé au soleil, notamment entre 10 et 14 heures; ■ et porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil.

Inactive or non-medicinal ingredients / Ingrédients non médicinaux : Aqua, caprylic/capric triglyceride, cetearyl alcohol, cetearyl glucoside, glyceryl isostearate, glyceryl stearate, C10-18 triglycerides, glycerin, polyhydroxystearic acid, ethylhexylglycerin, caprylyl glycol, xanthan gum, sodium gluconate.

Other Information / Autre information :

Store at temperatures below 90°F. / Entreposer à une température inférieure à 32°C



little ones · tout-petits



100% MINERAL

SUNSCREEN

fragrance-free · hypoallergenic BROAD SPECTRUM (UVA/UVB), NON NANO

DERMATOLOGICALLY TESTED

CRÈME SOLAIRE

100 % MINÉRALE

sans fragrance · hypoallergénique LARGE SPECTRE (UVA/UVB), NON NANO

TESTÉ SOUS CONTRÔLE DERMATOLOGIQUE



WORRY-FREE INGREDIENTS RASSURANTS

NPN 80047088 · 75 g / 2.6 0Z.



ATTITUDE MINERAL SUNSCREEN LITTLE ONES - FRAGRANCE FREE

zinc oxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:61649-001 **Route of Administration** TOPICAL

| Active Ingredient/Active Moiety | | |
|--|-------------------|---------------|
| Ingredient Name | Basis of Strength | Strength |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 20 g in 100 g |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| WATER (UNII: 059QF0KO0R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| CETEARYL GLUCO SIDE (UNII: 09 FUA 47 KNA) | |
| GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO) | |
| GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4) | |
| C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM GLUCONATE (UNII: R6Q3791S76) | |
| CAPRYLYL GLYCOL (UNII: 00 YIU5438 U) | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

| P | Packaging | | | |
|---|------------------|--|-----------------------------|---------------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61649-001-75 | 1 in 1 CARTON | 03/01/2014 | |
| 1 | | 75 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:61649-001-15 | 1 in 1 CARTON | 03/01/2014 | |
| 2 | | 150 g in 1 TUBE; Type 0: Not a Combination Product | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH NOT FINAL | part352 | 0 3/0 1/20 14 | |
| | | | |

Labeler - Bio Spectra (201137051)

Revised: 3/2017 Bio Spectra