# MINERAL WEAR- titanium dioxide, zinc oxide powder Mei Shual Cosmetics Co., Ltd.

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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# **Active Ingredients**

# **Purpose**

Titanium Dioxide 6.0%, Zinc Oxide 4.2% ...... Sunscreen

## $\Box$ 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.

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

Physicians Formula

Mineral Wear

Talc-Free Mineral Face Powder

SPF 16 Broad Spectrum Sunscreen

Minimalist formula helps reduce irritation & breakout.

Net Wt. 0.3 oz / 9g

For extra sensitive or breakout-prone skin!

Recommended as an effective broad spectrum sunscreen

HYPOALLERGENIC

FRAGRANCE FREE

**GLUTEN FREE** 

NON-COMEDOGENIC

**DERMATOLOGIST APPROVED** 

**Warnings For external use only** 

**Do not use** Ion damaged or broken skin

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

**Stop use and ask a doctor** lif rash occurs.

### **Directions**

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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 of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am 2pm
- wear long-sleeve pants, hats, and sunglasses

# **Inactive Ingredients:**

mica, squalane, silica, lauroyl lysine, boron nitride, kaolin, retinyl palmitate, tocopheryl acetate, dehydroacetic acid. may contain: titanium dioxide, iron oxides, chromium hydroxide green.

**Other Information:** Iprotect this product from excessive heat and direct sun

**Questions or comments?** □ Call toll-free 1-800-227-0333



# MINERAL WEAR titanium dioxide, zinc oxide powder Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

| Active Ingredient/Active Moiety  |                   |                |  |
|--|-------------------|----------------|--|
| Ingredient Name  | Basis of Strength | Strength       |  |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP) | TITANIUM DIO XIDE | 6 g in 100 g   |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)                | ZINC CATION       | 4.2 g in 100 g |  |

| Inactive Ingredients                           |          |
|--|----------|
| Ingredient Name                                | Strength |
| MICA (UNII: V8 A1AW0 880)                      |          |
| SQUALANE (UNII: GW89575KF9)                    |          |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)           |          |
| LAURO YL LYSINE (UNII: 113171Q70B)             |          |
| BORON NITRIDE (UNII: 2U4T60A6YD)               |          |
| KAOLIN (UNII: 24H4NWX5CO)                      |          |
| VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC)       |          |
| .ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)   |          |
| DEHYDRO ACETIC ACID (UNII: 2KAG279R6R)         |          |
| BROWN IRON OXIDE (UNII: 1N0 32N7MFO)           |          |
| CHROMIUM HYDRO XIDE GREEN (UNII: RV8 FT8 XF5R) |          |

| Packaging          |                     |                      |                    |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:69184-002-01 | 9 g in 1 PACKAGE    |                      |                    |

| Marketing Information |  |                      |                    |  |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |
| OTC monograph final   | part352                                  | 12/08/2014           |                    |  |
|                       |  |                      |                    |  |

# **Labeler** - Mei Shual Cosmetics Co., Ltd. (656375912)

| Establishment                 |         |           |                        |  |
|-------------------------------|---------|-----------|------------------------|--|
| Name                          | Address | ID/FEI    | Business Operations    |  |
| Mei Shual Cosmetics Co., Ltd. |         | 656375912 | manufacture(69184-002) |  |

Revised: 12/2014 Mei Shual Cosmetics Co., Ltd.