

**MALLY FACE DEFENDER FOUNDATION BB - titanium dioxide, zinc oxide cream**  
**MallyGirl, LLC**

*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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**Drug Facts**

**mally Face Defender BB - Tan**

**Active Ingredients**

Titanium Dioxide 4.50%

Zinc Oxide 3.00%

**Purpose**

Sunscreen

Sunscreen

**Use**

- 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.

**Stop use and ask doctor** if rash occurs.

**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
- 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 risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m.
- Wear long sleeved shirts, pants, hats and sunglasses

**Inactive Ingredients**

Water (Aqua), Cyclopentasiloxane, Octyldodecyl Neopentanoate, Butylene Glycol, Glycerin, Polyglyceryl-4 Isostearate, Dimethicone Crosspolymer, PEG/PPG 18/18 Dimethicone, Silica, Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Stearic Acid, Aluminum Hydroxide, Sodium Dehydroacetate, Phytantriol, Hexyl Laurate, Triethoxycaprylylsilane, Nylon-12, Carbomer, Polysorbate 20, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Chloride, Tocopherol, Tetrahexyldecyl Ascorbate, Nylon-12 Fluorescent Brightener 230 Salt, Polyvinylalcohol Crosspolymer, Magnesium Chloride, Potassium Chloride, Zinc Chloride, Lysine, Sodium Hyaluronate, Phenoxyethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate, May Contain: Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499)

#### **Other Information**

- Protect this product from excessive heat and direct sun.

Distributed by **Mallygirl LLC**

P.O. Box 42727

Baltimore, MD 21284-2727

Product made in USA

#### **Principal Display Panel**

mally

Face Defender BB

cream foundation

BROAD SPECTRUM SPF 15

Tube

**m a l l y**

**Face Defender BB**  
cream foundation

**BROAD SPECTRUM**  
**SPF 15**

FRONT PANEL

1.8 FL. OZ./53.2 ml

**ACTIVE INGREDIENTS:**

Titanium Dioxide 4.5%

Zinc Oxide 3.0%

**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.

For additional directions and  
product information, see back of  
outer carton or brochure provided  
with this product.

Dist. by **Mallygirl LLC**

P.O. Box 42727

Baltimore, MD 21284-2727

Made in USA

Box

## Drug Facts

| Active Ingredients      | Purpose   |
|-------------------------|-----------|
| Titanium Dioxide 4.51 % | Sunscreen |
| Zinc Oxide 3.10 %       | 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.

Stop use and ask doctor if rash occurs.

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. • 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 risk of skin cancer and early 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 10:00 a.m. - 2:00 p.m. • Wear long sleeved shirts, pants, hats and sunglasses

**Inactive Ingredients** Water (Aqua), Cyclopentasiloxane, Octyldodecyl Neopentanoate, Butylene Glycol, Glycerin, Polyglyceryl-4 Isostearate, Dimethicone Crosspolymer, PEG/PPG-18/18, Dimethicone, Silica, Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Stearic Acid, Aluminum Hydroxide, Sodium Dehydroacetate, Phytantriol, Hexyl Laurate, Triethoxypropylsilane, Nylon-12, Carbomer, Polysorbate 20, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Chloride, Tocopherol, Tetrahydroxyl Ascorbate, Nylon-12 Fluorescent Brightener 238 Salt, Polyvinylalcohol Crosspolymer, Magnesium Chloride, Potassium Chloride, Zinc Chloride, Lysine, Sodium Hyaluronate, Phenylethanol, Hexylene Glycol, Caprylyl Glycol, Potassium Sorbate. May Contain: Mica, Titanium Dioxide (CI 77891), Iron Oxides (CI 77491, CI 77492, CI 77499).

**Other Information** • Protect this product from excessive heat and direct sun.

Distributed by **Mallygirl LLC**  
PO: Box 43737 • Baltimore, MD 21214-3737  
Product made in USA • Brush made in China

mally

Face Defender BB  
cream foundation

BROAD SPECTRUM SPF 15

CONTAINS 1 BRUSH  
AND 1 CREAM FOUNDATION  
1.8 FL. OZ./53.2 ml

## MALLY FACE DEFENDER FOUNDATION BB

titanium dioxide, zinc oxide cream

### Product Information

|                         |                |                    |                 |
|-------------------------|----------------|--------------------|-----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:76 119-1445 |
| 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  | 2.39 mg in 53.2 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)               | ZINC OXIDE        | 1.59 mg in 53.2 mL |

### Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R)                                  |          |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)             |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)                        |          |
| GLYCERIN (UNII: PDC6A3C0OX)                               |          |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)             |          |
| PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)              |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                        |          |
| DIMETHICONE (UNII: 92RU3N3Y1O)                            |          |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                           |          |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)                     |          |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G)                  |          |
| PHYTANTRIOL (UNII: 8LVI07A72W)                            |          |
| HEXYL LAURATE (UNII: 4CG9F9W01Q)                          |          |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)                  |          |
| NYLON-12 (UNII: 446U8J075B)                               |          |
| CARBOMER 940 (UNII: 4Q93RCW27E)                           |          |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)                         |          |
| PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)                 |          |
| PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)               |          |
| SODIUM CHLORIDE (UNII: 451W47IQ8X)                        |          |
| TOCOPHEROL (UNII: R0ZB2556P8)                             |          |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)              |          |
| POLYVINYL ALCOHOL (UNII: 532B59J990)                      |          |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)                       |          |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O)                     |          |
| POTASSIUM CHLORIDE (UNII: 660YQ98H0)                      |          |
| ZINC CHLORIDE (UNII: 86Q357L16B)                          |          |
| LYSINE (UNII: K3Z4F929H6)                                 |          |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH)                     |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |          |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J)                        |          |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U)                        |          |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4)                      |          |
| MICA (UNII: V8A1AW0880)                                   |          |
| FERRIC OXIDE RED (UNII: 1K09F3G675)                       |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:76119-1445-1 | 1 in 1 BOX          |                      |                    |
| 1 |                  | 53.2 mL in 1 TUBE   |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 02/03/2014           |                    |

