

**MALLY FACE DEFENDER FOUNDATION - 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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**mally Face Defender - Tan Foundation Broad Spectrum SPF 15**

**DRUG FACTS**

**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.

**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) Product made in the USA

#### **Other Information**

- Protect this product from excessive heat and direct sun.

#### **Principal Display Panel**

mally  
Face Defender Foundation  
Tan  
Broad Spectrum  
SPF15

**m a l l y**

**Face Defender**  
foundation

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

FRONT PANEL

1.8 FL. OZ./53.2 ml

**ACTIVE INGREDIENTS:**

Titanium Dioxide 4.5%

Zinc Oxide 3.0%

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or broken skin.

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water to remove.

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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

Face Defender foundation with sunscreen

**Drug Facts**

Active Ingredients	Purpose
Titanium Dioxide 4.50 %	Sunscreen
Zinc oxide 3.00 %	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**

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- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: ask a doctor.
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  - 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 Dihydrosebacate, Phylanthrid, Hexyl Laurate, Triethoxyacrylylsilane, Nylon-12, Carbomer, Polysorbate 20, Palmitoyl Oligopeptide, Palmitoyl Tetrapeptide-7, Sodium Chloride, Tocopherol, Tetrahydroxyethyl 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). Product made in USA.

**Other Information**

- Protect this product from excessive heat and direct sun.

**NOURISHING CONCEALER INGREDIENTS:** HYDROGENATED POLYISOBUTENE, OCTYLDODECANOL, TALC, PENTERYTHRITYL TETRAOSTEARATE, DEXTRIN PALMITATE, DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE, PTFE, SYNTHETIC BEESWAX, POLYETHYLENE ETHYLENE/PROPYLENE COPOLYMER, DISTEARDIMONIUM HEPTORITE, HYDROGENATED STYRENEISOPRENE COPOLYMER, ALCOHOL, OCTYLDODECYL PCA, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROBINNANATE, DIPROPYLENE GLYCOL, WATER (AQUA), QUERCUS SUBER BARK EXTRACT. MAY CONTAIN: MICA (CI 77019), TITANIUM DIOXIDE (CI 77891), IRON OXIDES (CI 77491, CI 77492), ULTRAMARINES (CI 77007). Product made in Italy.

**MALLY FACE DEFENDER FOUNDATION**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76 119-1328
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.39 mL in 53.2 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1.59 mL in 53.2 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8 725R883T)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	

GLYCERIN (UNII: PDC6A3C0OX)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
POLYETHYLENE GLYCOL 900 (UNII: UEP843BRCQ)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
DIMETHICONE (UNII: 92RU3N3Y1O)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)
STEARIC ACID (UNII: 4ELV7Z65AP)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)
PHYTANTRIOL (UNII: 8LVI07A72W)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
NYLON-12 (UNII: 446U8J075B)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PALMITOYL OLIGOPEPTIDE (UNII: HO4ZT5S86C)
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TOCOPHEROL (UNII: R0ZB2556P8)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)
MAGNESIUM CHLORIDE (UNII: 02F3473H9O)
POTASSIUM CHLORIDE (UNII: 660YQ98I10)
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)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76119-1328-1	1 in 1 BOX		
1		59.2 mL in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/29/2012	

**Labeler** - MallyGirl, LLC (167262554)