

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.

Drug Facts

mally Face Defender BB - Medium

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%

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or broken skin.

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water to remove.

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Keep out of reach of children.

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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

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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:76 119-1443
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: 0THI5PCI0R)	
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:76119-1443-1	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	

