

**ESSENTIAL DEFENSE MINERAL SHIELD BROAD SPECTRUM SPF 35 SUNSCREEN-  
titanium dioxide and zinc oxide lotion  
Allergan, Inc.**

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**ESSENTIAL DEFENSE MINERAL SHIELD BROAD SPECTRUM SPF 35 SUNSCREEN  
Titanium dioxide and zinc oxide lotion  
*Drug Facts***

***Active ingredients***

Titanium Dioxide 5.0%

Zinc Oxide 6.0%

***Purpose***

Sunscreen

Sunscreen

***Uses***

- Helps prevent sunburn
- If used as directed with other sun protection measures (see *Directions*) decreases 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

**When using this product**

keep out of eyes. Rinse with water to remove.

**Stop use and ask a doctor**

if skin rash occurs

**Keep out of reach of children.**

If product is 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
- **Sun Protection Measures** Spending time in the sun increases the risk of skin cancer, premature skin aging and other skin damage. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including limiting time in the sun from 10 a.m.-2 p.m., and wearing protective clothing
- Children under 6 months: Ask a doctor

### ***Inactive ingredients***

Water, Cyclopentasiloxane, Dimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Butylene Glycol, Aluminum Hydroxide, Dimethicone/PEG-10/15 Crosspolymer, PEG-9 Polydimethylsiloxyethyl Dimethicone, Sodium Chloride, Caffeine, Camellia Oleifera Leaf Extract, Sodium Citrate, Dimethicone/Vinyl Dimethicone Crosspolymer, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Stearic Acid, Ethylhexylglycerin, Phenoxyethanol

### ***Other information***

- Protect this product from excessive heat and direct sun
- Store at room temperature 15° - 30°C (59° - 86°F)

### ***Questions or comments?***

[www.skinmedica.com](http://www.skinmedica.com)

### **Principal Display Panel - Carton Label**

SkinMedica®  
ESSENTIAL  
DEFENSE  
MINERAL SHIELD™  
BROAD SPECTRUM  
SPF 35  
SUNSCREEN  
POST-PROCEDURE &  
SENSITIVE SKIN  
SUN PROTECTION  
Net Wt. 1.85 Oz. / 52.5 g



## Principal Display Panel - Tube Label

SkinMedica®  
ESSENTIAL  
DEFENSE

MINERAL SHIELD™  
 BROAD SPECTRUM  
 SPF 35  
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 POST-PROCEDURE &  
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## ESSENTIAL DEFENSE MINERAL SHIELD BROAD SPECTRUM SPF 35 SUNSCREEN

titanium dioxide and zinc oxide lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:0023-5703

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	50 mg in 1 g
<b>Zinc oxide</b> (UNII: SOI2LOH54Z) (zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	60 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S)</b> (UNII: RLA2U05Z4Q)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077EL0C60)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CAFFEINE</b> (UNII: 3G6A5W338E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0023-5703-17	1 in 1 CARTON	03/16/2016	
1		52.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0023-5703-08	1 in 1 CARTON	03/16/2016	
2		227 g in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:0023-5703-25	6 in 1 CARTON	03/16/2016	
3		7.1 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 Drug	M020	03/16/2016	

