TOTAL DEFENSE REPAIR BROAD SPECTRUM SPF 34 SUNSCREEN- octinoxate, octisalate and zinc oxide lotion
Allergan, Inc.

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.

Total Defense Repair Broad Spectrum SPF 34 Sunscreen
Drug Facts

Active ingredients

Octinoxate 7.5%

Octisalate 3.0%

Zinc Oxide 8.0%

Purpose

Sunscreen

Sunscreen

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

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.

Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours and after towel drying, swimming, or sweating to avoid lowering protection
- **Sun Protection Measures** UV exposure from 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, Caprylic/Capric Triglyceride, Silica, Squalane, Glycerin, Niacinamide, Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Polygonum Aviculare Extract, Physalis Angulata Extract, Dunaliella Salina Extract, Ubiquinone, Camellia Sinensis Leaf Extract, Tremella Fuciformis Sporocarp Extract, Betaine, Melanin, Tocopheryl Acetate, Tocopherol, Hydroxyacetophenone, Batyl Alcohol, C12-15 Alkyl Benzoate, Panthenol, Butylene Glycol, Ceteareth-20, Polyhydroxystearic Acid, Isostearic Acid, Xanthan Gum, Ethylhexylglycerin, Disodium EDTA, Aminomethyl Propanol, Caprylyl Glycol, Potassium Sorbate, Sorbic Acid, Phenoxyethanol

Other information

- protect the product in this container from excessive heat and direct sun
- store at room temperature 15°- 30°C (59°- 86°F)

Questions or comments

www.skinmedica.com

Principal Display Panel - Carton Label

TOTAL DEFENSE
+
REPAIR
Broad Spectrum SPF 34 Sunscreen
+ INFRARED PROTECTION
Net Wt. 6 x 1.0 Oz. Travel

TOTAL DEFENSE REPAIR BROAD SPECTRUM SPF 34 SUNSCREEN

octinoxate, octisalate and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0023-5494
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	30 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
NIACINAMIDE (UNII: 25X51I8RD4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
DUNALIELLA SALINA (UNII: F4O1DKI9A6)	
UBIDECARENONE (UNII: EJ27X76M46)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TREMELLA FUCIFORMIS FRUITING BODY (UNII: GG8N28393G)	
BETAINE (UNII: 3SCV180C9W)	
MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
BATILOL (UNII: 39YR661C4U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PANTHENOL (UNII: WV9CM0O67Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

SORBIC ACID (UNII: X045WJ989B)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0023-5494-23	1 in 1 CARTON	06/15/2015	
1		65 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0023-5494-01	1 in 1 CARTON	06/15/2015	
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0023-5494-25	6 in 1 CARTON	06/15/2015	
3		7.08 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 not final	part352	06/15/2015	

Labeler - Allergan, Inc. (144796497)

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