

HA PHYSICAL TINT SPF 44- zinc oxide, titanium dioxide cream

Private Label Skin Care

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.

HA Physical Tint SPF 44

Drug Facts

Active Ingredients

Zinc Oxide 10%

Titanium Dioxide 5.5%

Purpose

Sunscreen

Use Helps prevent sunburn • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings For external use only.

When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician. Reapply after 80 minutes of swimming or sweating. Reapply immediately after towel drying at least every 2 hours.

Precautions • Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum value of SPF 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m.–2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a physician.

Inactive Ingredients Water, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Caprylyl Methicone, Iron Oxides, Glycerin, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Octyldodecyl Neopentanoate, Dimethicone, Alumina, Sodium Chloride, Sodium Hyaluronate, Tocopherol, Ascorbyl Palmitate, Ethylhexylglycerin, Methicone,

Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Distearidimonium Hectorite, Propylene Carbonate, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Phenoxyethanol

brand MD®

SKIN CARE

SUN DEFENSE

medical grade

✓ **Lightweight, physical sunscreen contains a moisturizing base and a sheer, universal tint**

✓ **Water resistant sunscreen (40 minutes)**

brandMD®

Chatsworth, CA 91311

www.brandMD.com

Toll Free: (877) 252-7546

Packaging



HA Physical Tint SPF 44

SUN DEFENSE
medical grade

- Lightweight, physical sunscreen contains a moisturizing base and a sheer, universal tint
- Water resistant sunscreen (40 minutes)

2.1 oz | 59 g

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 10%.....	Sunscreen
Titanium Dioxide 5.5%.....	Sunscreen

Use Helps prevent sunburn • If used as directed with other sun protection measures, decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings For external use only.

When using this product • keep out of eyes. Rinse with water to remove. Stop use and ask physician if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions • Apply to face and neck, avoiding the eye area. Wait at least 30 minutes before sun exposure, or as directed by a physician. Reapply after 80 minutes of swimming or sweating. Reapply immediately after towel drying at least every 2 hours.

Precautions • Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum value of SPF 15 or higher and other sun protection measures including: limit time in the sun, especially from 10 a.m.–2 p.m. wear long-sleeved shirts, pants, hats, and sunglasses. Children under 6 months of age: Ask a physician.

Inactive Ingredients Water, Cyclopentasiloxane, C12-15 Alkyl Benzoate, Caprylyl Methicone, Iron Oxides, Glycerin, Lauryl PEG-9 Polydimethylsiloxyethyl Dimethicone, Octyldodecyl Neopentanoate, Dimethicone, Alumina, Sodium Chloride, Sodium Hyaluronate, Tocopherol, Ascorbyl Palmitate, Ethylhexylglycerin, Methicone, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Disteardimonium Hectorite, Propylene Carbonate, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Phenoxyethanol

4531 v1



brandMD®
Chatsworth, CA 91311
www.brandMD.com
Toll Free: (877) 252-7546
Made in USA

HA PHYSICAL TINT SPF 44

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72957-006(NDC:39765-022)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	10 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	5.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
FERRIC OXIDE RED (UNII: 1K09F3G675)
GLYCERIN (UNII: PDC6A3C0OX)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
DIMETHICONE (UNII: 92RU3N3Y1O)
ALUMINUM OXIDE (UNII: LMI26O6933)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TOCOPHEROL (UNII: ROZB2556P8)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
METHICONE (20 CST) (UNII: 6777U11MKT)
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72957-006-01	59 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2020	

Labeler - Private Label Skin Care (116996962)

Establishment

Name	Address	ID/FEI	Business Operations
Private Label Skin Care		116996962	relabel(72957-006)