

ONALT PURE MILD SUNCREAM- titanium dioxide, zinc oxide cream
HnB9 Co., Ltd.

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.

titanium dioxide, zinc oxide

UV protection

skin whitening

wrinkle care

KEEP OUT OF REACH OF THE CHILDREN

- For external use only.
- Do not use in eyes.
- If swallowed, get medical help promptly.
- Stop use, ask doctor If irritation occurs.
- Keep out of reach of children.

for external use only

Water

C12-15 Alkyl Benzoate

Cyclopentasiloxane

Glycerin

Methylpropanediol

Cetyl PEG/PPG-10/1 Dimethicone

Aluminum Hydroxide

Polyhydroxystearic Acid

Niacinamide

Cetyl Dimethicone

Sea Water

Cetyl Ethylhexanoate

Sorbitan Trioleate

Stearic Acid

Isostearic Acid

Sorbitan Sesquioleate

Trifluoropropyl Dimethicone

Benzyl Glycol

Disteardimonium Hectorite

Ozokerite

Sodium Chloride

Butylene Glycol

Silica Dimethyl Silylate

Polymethylsilsesquioxane

Fragrance

Silica

Tocopheryl Acetate

Sargassum Fulvellum Extract

Ethylhexylglycerin

Hizikia Fusiforme Extract

1,2-Hexanediol
Adenosine
Disodium EDTA
Ethylhexylglycerin

apply proper amount to the skin

Drug Facts

Active Ingredients

Zinc Oxide 12%
Titanium Dioxide 10%

Purpose

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 physician if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Direction

- Apply liberally to face and neck 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 your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m - 2 p.m.
 - Wear long sleeve shirts, pants, hats, and sunglasses
 - Children under 6 months : Ask a physician

Inactive Ingredients

Water, C12-15 Alkyl Benzoate, Zinc Oxide, Titanium Dioxide, Cyclopentasiloxane, Glycerin, Methylpropanediol, Cetyl PEG/PPG-10/1 Dimethicone, Aluminum Hydroxide, Polyhydroxystearic Acid, Niacinamide, Cetyl Dimethicone, Sea Water, Cetyl Ethylhexanoate, Sorbitan Trioleate, Stearic Acid, Isostearic Acid, Sorbitan Sesquioleate, Trifluoropropyl Dimethicone, Benzyl Glycol, Distearidimonium Hectorite, Ozokerite, Sodium Chloride, Butylene Glycol, Silica Dimethyl Silylate, Polymethylsilsesquioxane, Fragrance, Silica, Tocopheryl Acetate, Sargassum Fulvellum Extract, Ethylhexylglycerin, Hizikia Fusiforme Extract, 1,2-Hexanediol, Adenosine, Disodium EDTA, Ethylhexylglycerin

Other information

- protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free +82-43-903-9651

Cosmetic manufacturer | HnB9 Co., Ltd
(Clean room) 9, Oksansandan 2-ro, Oksan-myeon,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-
do, Republic of Korea **MADE IN KOREA**

ONALT PURE MILD SUNCREAM

titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80564-0001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80564-0001-1	50 mL in 1 TUBE; Type 0: Not a Combination Product	09/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/22/2020	

Labeler - HnB9 Co., Ltd. (694434516)

Registrant - HnB9 Co., Ltd. (694434516)

Establishment

Name	Address	ID/FEI	Business Operations
HnB9 Co., Ltd.		694434516	manufacture(80564-0001)

Revised: 9/2020

HnB9 Co., Ltd.