

ATOMY SUNSCREEN WHITE BROAD SPECTRUM SPF 50 PLUS- homosalate, octisalate, titanium dioxide, zinc oxide cream
ATOMY 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.

ACTIVE INGREDIENTS

HOMOSALATE 7.50%
OCTISALATE 4.50%
TITANIUM DIOXIDE 2.20%
ZINC OXIDE 12.70%

INACTIVE INGREDIENTS

Aqua/Water/Eau, Cyclopentasiloxane, Dipropylene Glycol, Disiloxane, Lauryl Peg-10 Tris(Trimethylsiloxy)Silylethyl Dimethicone, Glycerin, Niacinamide, Propylheptyl Caprylate, Portulaca Oleracea Extract, Silica, Dimethicone, Disteardimonium Hectorite, Magnesium Sulfate, 1,2-Hexanediol, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Triethoxycaprylylsilane, Aluminum Hydroxide, Stearic Acid, Sorbitan Caprylate, Dimethicone/Peg-10/15 Crosspolymer, Fragrance(Parfum), Dimethicone/Vinyl Dimethicone Crosspolymer, Glyceryl Caprylate, Ethylhexylglycerin, Adenosine, Tocopherol, Camellia Sinensis Leaf Extract, Melissa Officinalis Extract, Centella Asiatica Extract, Perilla Ocymoides Leaf Extract

PURPOSE

Sunscreen

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.

DESCRIPTION

Directions:

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water-resistant sunscreen if swimming or sweating

- Children under 6 months: Ask a doctor

- **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 value 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-sleeved shirts, pants, hats, and sunglasses

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

Other Information:

Protect this product from excessive heat and direct sun

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

ATOMY SUNSCREEN WHITE
Broad Spectrum SPF 50+

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ATOMY

ATOMY SUNSCREEN WHITE
Broad Spectrum SPF 50+

Drug Facts

Active Ingredient	Purpose
Homosalate 7.50%	SUNSCREEN
Octisalate 4.5%	
Titanium Dioxide 2.20%	
Zinc Oxide 12.70%	

Uses

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- 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

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Directions

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water-resistant sunscreen if swimming or sweating
- children under 6 months: Ask a doctor
- **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 value 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-sleeved shirts, pants, hats, and sunglasses

Imported & Distributed By:

Atomy America Inc.
33801 1st Way South, Suite #301
Federal Way, WA 98003
TEL : +1-253-946-2344
www.atomy.com/us

R&D CENTER
KOLMAR BNH CO., LTD.
MANUFACTURER
KOLMAR KOREA CO., LTD.

See bottom of the container for lot number and expiration date.

MADE IN KOREA



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ATOMY SUNSCREEN
Broad Spectrum SPF 50+

Broad Spectrum Sunscreen
Helps protect skin from UVA/UVB rays

2 FL. OZ. (60 mL)

Drug Facts

(continued)

Other information

- protect this product from excessive heat and direct sun

Inactive Ingredients

1,2-Hexanediol, Adenosine, Aluminum Hydroxide, Aqua/Water/Eau, Camellia Sinensis Leaf Extract, Centella Asiatica Extract, Cyclopentasiloxane, Dimethicone, Dimethicone/PEG-10/15 Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dipropylene Glycol, Disiloxane, Distearidimonium Hectorite, Ethylhexylglycerin, Fragrance(Parfum), Glycerin, Glyceryl Caprylate, Lauryl PEG-10 Tris(trimethylsiloxy) Silylethyl Dimethicone, Magnesium Sulfate, Melissa Officinalis Extract, Niacinamide, Perilla Ocymoides Leaf Extract, Portulaca Oleracea Extract, Propylheptyl Caprylate, Silica, Sorbitan Caprylate, Stearic Acid, Tocopherol, Triethoxycaprylylsilane, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

US11-060821

ATOMY SUNSCREEN WHITE BROAD SPECTRUM SPF 50 PLUS

homosalate, octisalate, titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52257-1410
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	4.5 g in 60 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.7 g in 60 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.32 g in 60 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	7.62 g in 60 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
Dipropylene Glycol (UNII: E107L85C40)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52257-1410-1	60 mL in 1 CARTON; Type 0: Not a Combination Product	06/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2021	

Labeler - ATOMY CO., LTD. (631154601)

Registrant - ATOMY CO., LTD. (631154601)

Establishment

Name	Address	ID/FEI	Business Operations
Kolmar Korea Co.,LTD. Gwanjeong Factory		689512611	manufacture(52257-1410)

