

ULTRA SUNSCREEN- octinoxate, octisalate, titanium dioxide emulsion
Jiangsu Senwo Medical Technology Co., Ltd.

85448-003 Ultra Sunscreen

Methoxy cinnamic acid ethylhexyl ester 7.5%
Diethanolamine hydroxybenzyl benzoate 3.5%
Octyl methoxycinnamate 1.5%
Titanium dioxide 2.7%

Sunscreen

Soothing + Moisturizing

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. May stain some fabrics.

Shake well.

Apply liberally 15 minutes before sun exposure.

Reapply: after 80 minutes of swimming or sweating, immediately after towel drying, 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 value of 15 or higher and other sunprotection 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: Ask a doctor.

Water, Glycerin, Methylpropanediol, Dibutyl Adipate, Alcohol, Ammonium PolyacryloyldimethylTaurate, Octyldodecyl Neopentanoate, 1,2-Hexanediol, Hydroxyacetophenone, Olive OilPolyglyceryl-6 Esters, Sorbitan Sesquioleate, Trideceth-10, Polyglyceryl-2Dipolyhydroxystearate, Polyglyceryl-6 Oleate, Sodium Polyacryloyldimethyl Taurate, C13-16Isoparaffin, Bisabolol, Polyglyceryl-10 Myristate, Fragrance, Allantoin, Polyglyceryl-3 Distearate, Aluminum Hydroxide, Stearic Acid, Hydrolyzed Sodium Hyaluronate, Butylene Glycol, 1,2-Pentenediol, Bacillus/Soybean Ferment Extract, Folic Acid, Sodium Hyaluronate



Ultra Sunscreen

Soothing + Moisturizing

SPF50

**Broad-Spectrum UVA/UVB
Sweat & Water-Resistant**

Family Size

16 FL. OZ. (473 mL)

DRUG FACTS

Active Ingredients	Purpose
▪ Methoxy cinnamic acid ethylhexyl ester.....	7.50% Sunscreen
▪ Diethanolamine hydroxybenzyl benzoate.....	3.50% Sunscreen
▪ Octyl methoxycinnamate.....	1.50% Sunscreen
▪ Titanium dioxide.....	2.70% Sunscreen

Inactive Ingredients:
 Water, Glycerin, Methylpropanediol, Dibutyl Adipate, Alcohol, Ammonium Polyacryloyldimethyl Taurate, Octyldodecyl Neopentanoate, 1,2-Hexanediol, Hydroxyacetophenone, Olive Oil Polyglyceryl-6 Esters, Sorbitan Sesquioleate, Trideceth-10, Polyglyceryl-2 Dipolyhydroxystearate, Polyglyceryl-6 Oleate, Sodium Polyacryloyldimethyl Taurate, C13-16 Isoparaffin, Bisabolol, Polyglyceryl-10 Myristate, Fragrance, Allantoin, Polyglyceryl-3 Distearate, Aluminum Hydroxide, Stearic Acid, Hydrolyzed Sodium Hyaluronate, Butylene Glycol, 1,2-Pentanediol, Bacillus/Soybean Ferment Extract, Folic Acid, Sodium Hyaluronate

Directions

- Shake well.
- Apply liberally 15 minutes before sun exposure.
- Reapply: after 80 minutes of swimming or sweating, immediately after towel drying, 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 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. Children under 6 months: Ask a doctor.

Warnings

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Customer Care Help Line:
 1-888-372-1450

Manufactured for: FSA Store Inc.
 5473 Blair Rd , Suite 100 , PMB 24308 , Dallas , TX 75231

Made in China
 Exp Date: 2027/12/30
 Manufacturing Date: 2025/12/30



ULTRA SUNSCREEN

octinoxate, octisalate, titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85448-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.09 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	0.035 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	0.027 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
FOLIC ACID (UNII: 935E97BOY8)	
HYDROLYZED SODIUM HYALURONATE 10 (UNII: AAZ2QV38TA)	
BISABOLOL (UNII: 24WE03BX2T)	
BACILLUS PUMILUS (UNII: FLS0C20S53)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
OLIVE OIL POLYGLYCERYL-6 ESTERS (UNII: 4KDO9AFM9I)	
SODIUM POLYACRYLOYLDIMETHYL TAURATE (UNII: NG5NG5733T)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (UNII: F01RIY4371)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
TRIDECETH-10 (UNII: G624N6MSBA)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYGLYCERYL-10 MYRISTATE (UNII: Y9WL8QN3ZB)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
POLYGLYCERYL-6 OLEATE (UNII: G4AYJ54K59)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85448-003-01	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/07/2026	

Labeler - Jiangsu Senwo Medical Technology Co., Ltd. (569521612)

Establishment

Name	Address	ID/FEI	Business Operations
Jiangsu Senwo Medical Technology Co., Ltd.		569521612	manufacture(85448-003)

Revised: 4/2026

Jiangsu Senwo Medical Technology Co., Ltd.