

TOTAL PROTRECTOR 15 - octinoxate, zinc oxide cream
MD Formulation

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.

Sun Total Protector 15

Octinoxate - 7.5% Sunscreen
Zink Oxide - 4.9% Sunscreen

When using this product do not use in or near the eyes.If product gets into eyes, rlirse thoroughly with water.

Warnings: For external use only.

Stop use and ask a doctor if Irritation or rash appears and lasls.

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

Directions: Children under 2 years of age should use sunscreen products with a minimum SPF of 4.
Adult and children 6 months and over: apply liberally 15 minutes before sun or water exposure; reapply after swimming or excessive sweating or anytime after towel drying . Children under 6 months ask a doctor.

Other information store at 20.25C (68-770 F)

Sun Alert: The sun causes sun damage. Regular use of sunscreens over the years may reduce the chance of skIn damage, some types of skin cancer, and other harmful effects due to the sun.

Inactive ingredients: Water (Aqua), Glyceryl Stearate, C12-15 Alkyl Benzoate, GlycerIn, Steareth-2, Steareth-100, Tricontanyl PVP, PEG-100 Stearate, Tocopheryl Acetate, Allantoin, Xanthan Gum, Cetyl Hydroxyethylcellulose, Dimethicone, Disodium EDTA, Diazolidinyl Urea, Iodopropynyl Butylcarbamate, Methylparaben. Propylparaben.

Provide skin with daily, year-round protection against sun exposure.

NDC 66078-110-25



Drug Facts	
Active Ingredient	Purpose
Octinoxate - 7.5%	Sunscreen
Zinc Oxide (CI 77947) - 4.9%	Sunscreen
Uses to help prevent sunburn and for the temporary protection of sunburn.	
Warnings For external use only.	
When using this product do not use in or near the eyes. If product gets into eyes, rinse thoroughly with water.	
Stop use and ask a doctor if irritation or rash appears and lasts.	
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.	
See Carton for complete information	



FACE / VISAGE

SUN

total protector 15
total daily protection

écran haute
protection 15
protection quotidienne

75ml (2.5fl. oz.)

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SPF 15

F PRODUIT DE TRAITEMENT PROFESSIONNEL

Cette formule non grasse multi-actions apporte à la peau, tout au long de l'année, la protection quotidienne dont elle a besoin pour lutter contre les rayons du soleil. L'oxyde de zinc micronisé protège la peau contre les UVA et UVB. La vitamine E et l'allantoïne apaisent et adoucissent. La Skin Cancer Foundation (Fondation pour le cancer de la peau) recommande l'utilisation de ce produit comme écran solaire sûr et efficace.

- testé sous contrôle dermatologique
- non-comédogène
- hypoallergénique
- sans parfum

Utilisation: Appliquer sur le visage, le cou, la poitrine et les mains, même sous le maquillage. Renouveler l'application avant toute exposition au soleil, après avoir nagé, transpiré ou s'être éponge à l'aide d'une serviette. Il est recommandé d'utiliser des produits avec écran solaire SPF 4 minimum chez les enfants de moins de 2 ans.

Méfaits du soleil: Le soleil peut être dangereux pour la peau. L'utilisation régulière d'écrans solaires peut réduire les risques de cancers de la peau et autres effets nocifs provoqués par le soleil sur la peau.

Précautions d'emploi: À usage externe seulement. Éviter tout contact avec les yeux. En cas d'irritation, rincer abondamment, interrompre l'utilisation du produit et consulter un médecin. Arrêter toute utilisation en cas d'apparition de signes d'irritation ou de rougeurs. Ne pas utiliser chez les enfants de moins de 6 mois sans avis médical.

md formulations®

SUN

total protector 15
total daily protection
all skin types
all weather

écran haute
protection 15
protection quotidienne
tout type de peau
tout climat

FACE / VISAGE

75 ml (2.5 fl. oz.)

ES PRODUCTO PARA TRATAMIENTO PROFESIONAL

Proteja diariamente su piel, durante todo el año, de la exposición solar con esta fórmula no grasa de amplio espectro. El óxido de zinc micronizado protege la piel de los rayos UVA y UVB, mientras que la vitamina E y la alantoína calman y suavizan la piel. La Fundación de Lucha contra el Cáncer de Piel recomienda este producto como una segura y efectiva pantalla contra los rayos UV.

- dermatológicamente testada
- no comedogénica
- hipoalérgica
- libre de fragancia

Modo de uso: Aplique sobre rostro, cuello, pecho y manos, y bajo el maquillaje. Reaplique antes de exponerse al sol, después de nadar, transpirar o de secarse con una toalla. Los niños menores de 2 años deben usar productos con pantallas solares con un factor de protección mínimo de 4.

Advertencia: El sol daña la piel. El empleo regular de pantallas solares puede reducir la probabilidad de daños a la piel, de algunos tipos de cáncer de piel y de otros efectos perjudiciales del sol.

Precaución: Sólo para uso externo. Evite que penetre en los ojos. Si se produce irritación, enjuague bien el producto, suspenda su uso y consulte un médico. Suspense si aparecen síntomas de irritación o urticaria. Emplee en niños menores de 6 meses sólo con recomendación médica.

US PROFESSIONAL TREATMENT PRODUCT

Provide skin with daily, year-round protection against sun exposure. Micronized zinc oxide protects skin from UVA and UVB rays while vitamin E and allantoin soften and soothe.

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TOTAL PROTRECTOR 15

octinoxate, zinc oxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:66078-110

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	4.9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL HYDROXYETHYLCELLULOSE (350000 MW) (UNII: T7SWE4S2TT)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
STEARETH-2 (UNII: V56DFE46J5)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARETH-100 (UNII: 4OH5W9UM87)	
TRIACONTANYL PVP (WP-660) (UNII: N0SS3Q238D)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66078-110-25	42 in 1 CASE		
1		1 in 1 CARTON		
1		78 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/08/2007	

Labeler - MD Formulation (087008363)

Registrant - Ei Inc (105803274)

Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 7/2012

MD Formulation