

**BRONZ REPAIR SEA AND TROPICS FACE SPF 25- octinoxate, avobenzone cream
NAOS**

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.

BRONZ REPAIR SEA AND TROPICS FACE SPF 25

Drug Facts

Active Ingredients

Octinoxate 6%

Avobenzone 2.6%

Purpose

Sunscreen

Uses

- Help prevent sunburn.

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 reach of children.

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Apply liberally, and spread evenly by hand 15 min before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating
- ***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-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months of age: Ask a doctor.

Other information

- Keep the product between 15-30°C.
- Protect the product in this container from excessive heat and direct sun.

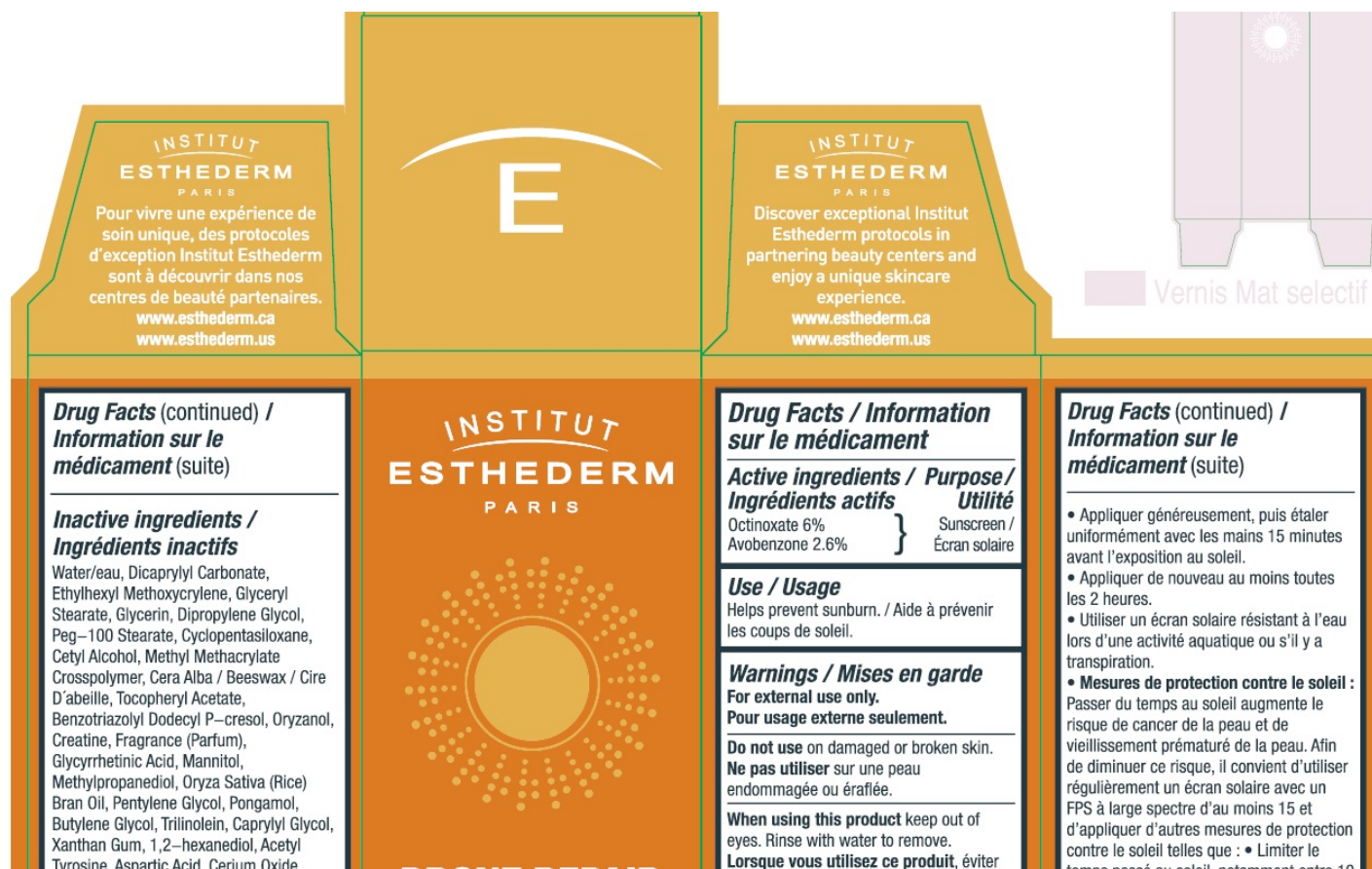
Question or comments?

Call to 1 877 443 3762

Inactive Ingredients

Water, Dicaprylyl Carbonate, Ethylhexyl Methoxycrylene, Glyceryl Stearate, Glycerin, Dipropylene Glycol, Peg-100 Stearate, Cyclopentasiloxane, Cetyl Alcohol, Methyl Methacrylate Crosspolymer, Cera Alba/Beeswax / Cire D'abeille, Tocopheryl Acetate, Benzotriazolyl Dodecyl P-cresol, Oryzanol Creatine, Fragrance (Parfum), Glycyrrhetic Acid, Mannitol, Methylpropanediol, Oryza Sativa (Rice) Bran Oil, Pentylene Glycol, Pongamol, Butylene Glycol, Trilinolein, Caprylyl Glycol, Xanthan Gum, 1,2-hexanediol, Acetyl Tyrosine, Aspartic Acid, Cerium Oxide, Potassium Cetyl Phosphate, Helianthus Annuus (Sunflower) Seed Oil, Polyethylene, Disodium Edta, Hydrogenated Castor Oil, Sodium Dextran Sulfate, Polysilicone-11, Sodium Hydroxide, Hydrolyzed Soy Protein, Oleoyl Tyrosine, Potassium Sorbate, Triolein, Tripalmitin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Hydrolyzed Wheat Protein, Oleic Acid, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Medicago Sativa (Alfalfa) Extract, Trilinolenin, Phenoxyethanol, Propylene Glycol, Alcohol, Carbomer, Sodium Lactate, Tristearin, Tris(Tetramethylhydroxypiperidinol) Citrate, Polysorbate 20, Copper Gluconate, Bht, Asiaticoside, Artemia Extract, Madecassic Acid, Carnosine, Tocopherol, Asiatic Acid, Triarachidin, Disodium Adenosine Triphosphate, Laminaria Digitata Extract, Palmitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Acetyl Hexapeptide-1, Dextran, Red 33 (CI 17200), Linalool, Hexyl Cinnamal, Hydroxycitronellal, Limonene, Benzyl Benzoate, Geraniol, Citronellol, Isoeugenol, Coumarin, Citral..

Package Labeling:



Potassium Cetyl Phosphate, Helianthus Annuus (Sunflower) Seed Oil, Polyethylene, Disodium Edta, Hydrogenated Castor Oil, Sodium Dextran Sulfate, Polysilicone-11, Sodium Hydroxide, Hydrolyzed Soy Protein, Oleoyl Tyrosine, Potassium Sorbate, Triolein, Tripalmitin, Acrylates/ C10-30 Alkyl Acrylate Crosspolymer, Hydrolyzed Wheat Protein, Oleic Acid, Pentaerythrityl Tetra-di-t-butyl Hydroxyhydrocinnamate, Medicago Sativa (Alfalfa) Extract, Trilinolenin, Phenoxyethanol, Propylene Glycol, Alcohol, Carbomer, Sodium Lactate, Tristearin, Tris (Tetramethylhydroxypiperidinol) Citrate, Polysorbate 20, Copper Gluconate, Bht, Asiaticoside, Artemia Extract, Madecassic Acid, Carnosine, Tocopherol, Asiatic Acid, Triarachidin, Disodium Adenosine Triphosphate, Laminaria Digitata Extract, Palamitoyl Tripeptide-1, Palmitoyl Tetrapeptide-7, Acetyl Hexapeptide-1, Dextran, Red 33 (Ci 17200), Linalool, Hexyl Cinnamal, Hydroxycitronellal, Limonene, Benzyl Benzoate, Geraniol, Citronellol, Isoeugenol, Coumarin, Citral.

Questions?

Call / Composez le 1-877-443-3762

BRONZ REPAIR CREAM / CRÈME

Sea And Tropics
Face · Anti-Wrinkles

Mer Et Tropiques
Visage · Anti-rides



SPF / FPS 25

Broad Spectrum
Sunscreen

Écran solaire
à large spectre

PROTECTION UVA—UVB PROTECTION

1.7 fl.oz.

50 mL

DIN : 02455250

tout contact avec les yeux. En cas de contact, rincer avec de l'eau.

Stop use and ask a doctor if rash occurs. Cessez d'utiliser ce produit et consultez un médecin en cas d'éruption cutanée.

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

Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison.

Directions / Mode d'emploi

- Apply liberally and spread evenly by hand 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if swimming or sweating.
- **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-sleeve shirts, pants, hats and sunglasses.
- Children under 6 months of age: ask a doctor. /

temps passe au soleil, notamment entre 10 et 14 heures. • Porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil. • Pour les enfants de moins de 6 mois : demander l'avis d'un médecin.

Other information / Autres renseignements

- Keep the product between 15–30°C (59–86°F).
- Protect the product in this container from excessive heat and direct sun.
- Garder le produit entre 15–30°C (59–86°F).
- Tenir loin de la chaleur excessive ou des rayons du soleil.

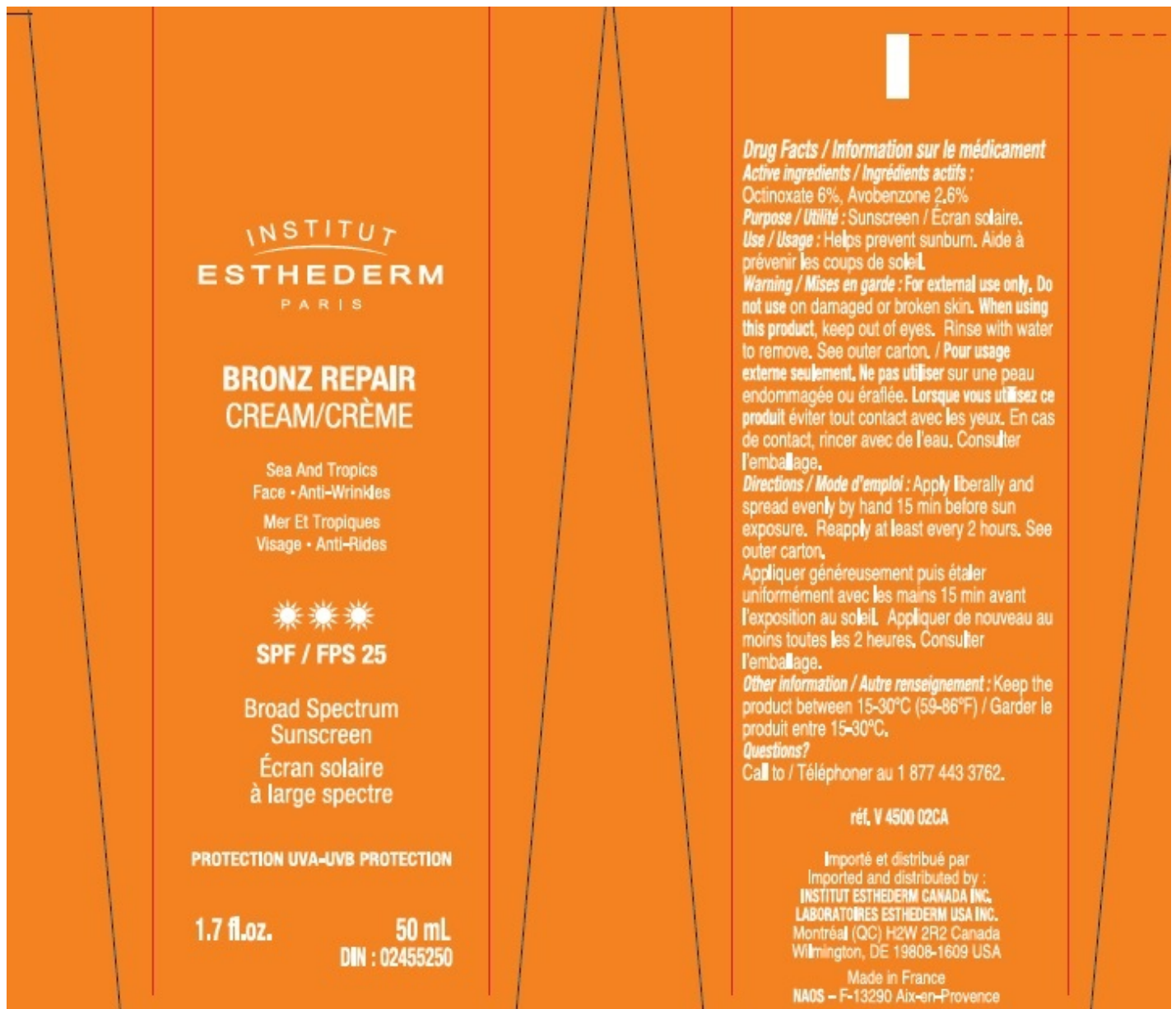
Réf : V 4500 02CA

Importé et distribué par/Imported and distributed by :
INSTITUT ESTHEDERM CANADA INC.
LABORATOIRES ESTHEDERM USA INC.
Montréal (QC) H2W 2R2 Canada
Wilmington, DE 19808-1609 USA

Made in France
NAOS
F-13290 Aix-en Provence



N1ET4500CAV5



BRONZ REPAIR SEA AND TROPICS FACE SPF 25
 octinoxate, avobenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14324-015
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		

WATER (UNII: 059QF0KO0R)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WHITE WAX (UNII: 7G1J5DA97F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BENZOTRIAZOLYL DODECYL P-CRESOL (UNII: 298PX4M11X)	
ENOXOLONE (UNII: P540XA09DR)	
MANNITOL (UNII: 3OWL53L36A)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
WHITE RICE (UNII: A195V20H7A)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PONGAMOL (UNII: 8Y19QCY6I4)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TRILINOLEIN (UNII: V5LJ52OGS7)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
N-ACETYLTYROSINE (UNII: DA8G610ZO5)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	
CERIC OXIDE (UNII: 619G5K328Y)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	
OLEOYL TYROSINE (UNII: 131PIBQX1U)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCERYL TRIOLEATE (UNII: O05EC62663)	
TRIPALMITIN (UNII: D133ZRF50U)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC; 3000 MW) (UNII: J2S07SB0YL)	
OLEIC ACID (UNII: 2UM9U37CP)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
ALFALFA (UNII: DJO934BRBD)	
TRILINOLENIN (UNII: OI7S0A9873)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALCOHOL (UNII: 3K9958V90M)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MMB07FC)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	

TRISTEARIN (UNII: P6OCJ2551R)
TRIS(TETRAMETHYLHYDROXYPIPERIDINOL) CITRATE (UNII: 7NW772I64Y)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
COPPER GLUCONATE (UNII: RV823G6G67)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
ASIATICOSIDE (UNII: PKO39VY215)
MADECASSIC ACID (UNII: M7O1N24J82)
CARNOSINE (UNII: 8HO6PVN24W)
TOCOPHEROL (UNII: R0ZB2556P8)
ASIATIC ACID (UNII: 9PA5A687X5)
TRIARACHIDIN (UNII: 48RPR95FW8)
ADENOSINE TRIPHOSPHATE DISODIUM (UNII: 5L51B4DR1G)
LAMINARIA DIGITATA (UNII: 15E7C67EE8)
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
CYCLOHEXYL CINNAMATE (UNII: 2955WP594O)
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL BENZOATE (UNII: N863NB338G)
GERANIOL (UNII: L837108USY)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)
ISOEUGENOL (UNII: 5M0MWY797U)
COUMARIN (UNII: A4VZ22K1WT)
CITRAL (UNII: T7EU0O9VPP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14324-015-00	1 in 1 BOX	01/31/2018	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/31/2018	

Labeler - NAOS (263520841)