

DR.ALTHEA DOUBLE SERUM BALM FOUNDATION 23- octinoxate, octisalate, titanium dioxide, homosalate cream
Dr.Althea 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.

70905-0019_Dr.Althea Double Serum Balm Foundation 23

Octinoxate 7.00%

Octisalate 4.80%

Titanium Dioxide 4.56%

Homosalate 2.50%

Sunscreen

Helps prevent sunburn

Apply liberally 15 minutes before sun exposure. Reapply at least every two 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: 1) Limited time in the sun, especially from 10 am to 2 pm. 2) Wear long-sleeve shirts, pants, hats, and sunglasses

Ask a doctor to use for children under 6 months

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.

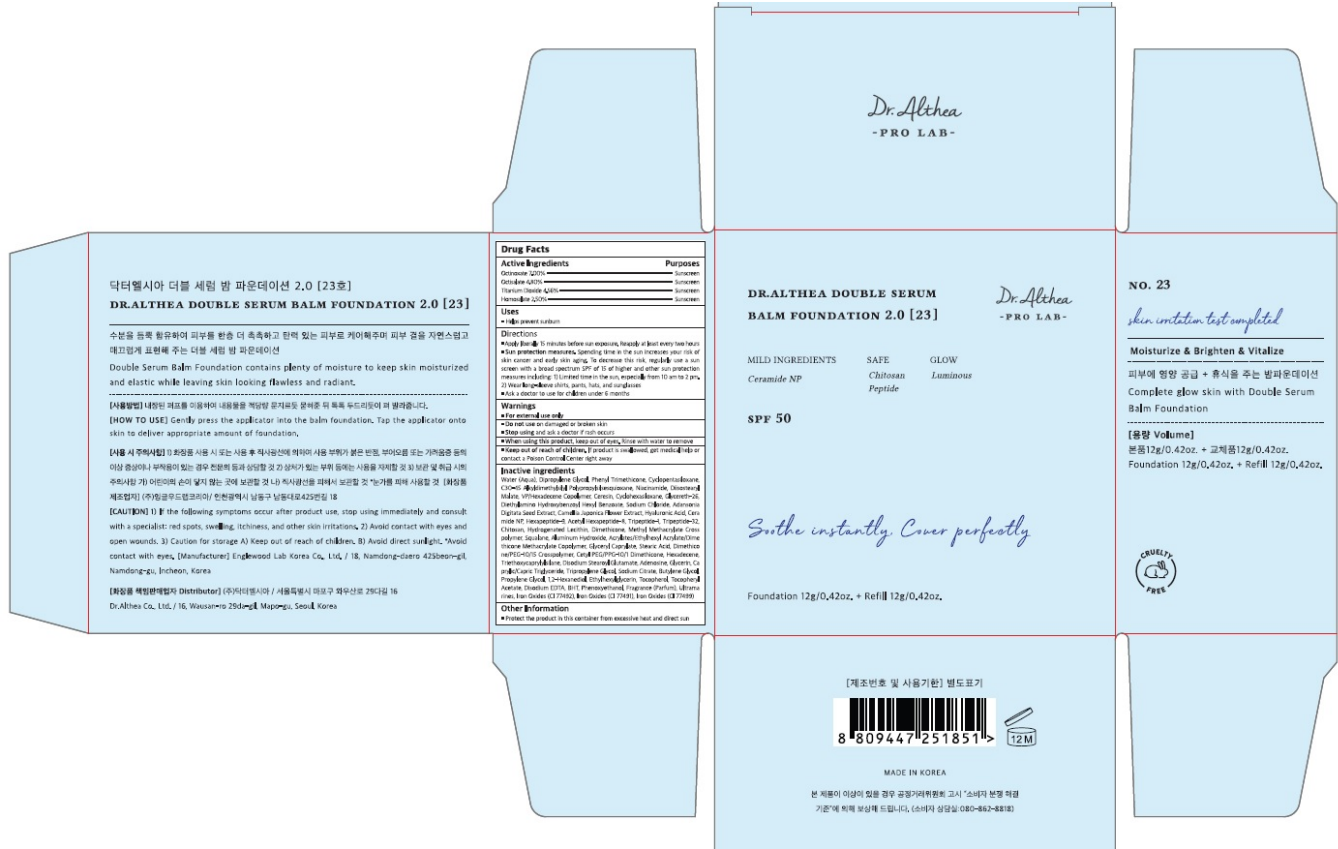
Stop using and ask a doctor if rash occurs.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water (Aqua), Dipropylene Glycol, Phenyl Trimethicone, Cyclopentasiloxane, C30-45 Alkyldimethylsilyl Polypropylsilsesquioxane, Niacinamide, Diisostearyl Malate, VP/Hexadecene Copolymer, Ceresin, Cyclohexasiloxane, Glycereth-26, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Sodium Chloride, Adansonia Digitata Seed Extract, Camellia Japonica Flower Extract, Hyaluronic Acid, Ceramide NP, Hexapeptide-9, Acetyl Hexapeptide-8, Tripeptide-1, Tripeptide-32, Chitosan, Hydrogenated Lecithin, Dimethicone, Methyl Methacrylate Crosspolymer, Squalane, Aluminum Hydroxide, Acrylates/Ethylhexyl Acrylate/Dimethicone Methacrylate Copolymer, Glyceryl Caprylate, Stearic Acid, Dimethicone/PEG-10/15 Crosspolymer, Cetyl PEG/PPG-10/1 Dimethicone, Hexadecene, Triethoxycaprylylsilane, Disodium Stearoyl Glutamate, Adenosine, Glycerin, Caprylic/Capric Triglyceride, Tripropylene Glycol, Sodium Citrate, Butylene Glycol, Propylene Glycol, 1,2-Hexanediol, Ethylhexylglycerin, Tocopherol, Tocopheryl Acetate, Disodium EDTA, BHT, Phenoxyethanol, Fragrance (Parfum), Ultramarines, Iron Oxides

(CI 77492), Iron Oxides (CI 77491), Iron Oxides (CI 77499)

Protect the product in the container from excessive heat and direct sun



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octinoxate, octisalate, titanium dioxide, homosalate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70905-0019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.56 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.5 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	4.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	

NIACINAMIDE (UNII: 25X51I8RD4)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
CERESIN (UNII: Q1LS2UJ03A)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
GLYCERETH-26 (UNII: NNE56F2N14)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
DIMETHICONE (UNII: 92RU3N3Y10)
SQUALANE (UNII: GW89575KF9)
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)
FERRIC OXIDE RED (UNII: 1K09F3G675)
STEARIC ACID (UNII: 4ELV7Z65AP)
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
HEXADECENE (MIXED ISOMERS) (UNII: 38H8547VP0)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70905-0019-2	2 in 1 CARTON	12/08/2021	
1	NDC:70905-0019-1	12 g in 1 CONTAINER; 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	12/08/2021	

Labeler - Dr.Althea Co.,Ltd (689694436)

Registrant - Dr.Althea Co.,Ltd (689694436)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, Inc.		080987545	manufacture(70905-0019)

