MISSHA M PRISM BRIGHT ON AUTO NO.2 SPF35 PA PLUS PLUS PLUS- titanium dioxide, octinoxate, zinc oxide powder ABLE C&C 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 INGREDIENT

ACTIVE INGREDIENTS: Titanium Dioxide 8.54%, Ethylhexyl Methoxycinnamate 6%, Zinc Oxide 2.94%

INACTIVE INGREDIENT

INACTIVE INGREDIENTS:

Talc, Mica, Nylon-12, Silica, Methyl Methacrylate Crosspolymer, Magnesium Myristate, Diisostearyl Malate, Phenyl Trimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Synthetic Beeswax, Pearl Powder, Plukenetia Volubilis Seed Oil, Lilium Candidum Flower Extract, Iris Versicolor Extract, Leontopodium Alpinum Flower/Leaf Extract, Nelumbo Nucifera Flower Extract, Rose Extract, Jasminum Officinale (Jasmine) Flower/Leaf Extract, Freesia Refracta Extract, Narcissus Pseudo-Narcissus (Daffodil) Flower Extract, Triethylhexanoin, Magnesium Stearate, Triethoxycaprylylsilane, Dimethicone, Methicone, Ethylhexylglycerin, Glyceryl Caprylate, Stearic Acid, Myristoyl/Palmitoyl Oxostearamide/Arachamide MEA, Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer, Phytosterols, Sodium Hyaluronate, Water, Butylene Glycol, Cetearyl Alcohol, Fragrance(Parfum), Iron Oxides

PURPOSE

PURPOSE: This combination of Cosmetic / OTC Drug can be used as a sunscreen and as a cosmetic to cover your blemishes / scar and to tone up your skin care.

WARNINGS

WARNING:

For external use only.

Do not swallow.

Keep out of reach of children.

Avoid contact with eyes.

Do not use on exposed wounds or if you are allergic to any ingredients of this product.

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS AND USAGE

INDICATION AND USAGE:

- Step 1. Take an appropriate amount of powder onto vibrating puff and dab it on forehead, cheek and chin.
- Step 2. Turn on the vibrating puff and spread the powder evenly on face.
- Step 3. Turn off the vibrating puff to stop.
- How to replace the puff

- Step 1. Hold the body of vibrating puff and slowly pull out the end to separate.
- Step 2. Place the new puff in the casing.
- Step 3. Press down on the puff to fix and arrange the edges.
- How to replace the battery
- Step 1. Hold the body of vibrating puff and slowly pull out the end to separate.
- Step 2. Twist the body of vibrating puff to separate. (Do not twist the vibrator inside to avoid damage)
- Step 3. Replace Lithium battery.

DOSAGE AND ADMINISTRATION

DOSAGE AND ADMINISTRATION:

Take appropriate amount according to your skin condition and apply as you desire. Remove it before sleeping.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



MISSHA M PRISM BRIGHT ON AUTO NO.2 SPF35 PA PLUS PLUS PLUS

titanium dioxide, octinoxate, zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13733-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	0.81 g in 9.5 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.57 g in 9.5 g	
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.28 g in 9.5 g	

Inactive Ingredients		
Ingredient Name	Strength	
Talc (UNII: 7SEV7J4R1U)		
Mica (UNII: V8A1AW0880)		
Magnesium Myristate (UNII: Z1917F0578)		
Dimethicone (UNII: 92RU3N3Y1O)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:13733-017-01	9.5 g in 1 CARTON		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 3/0 1/20 12	

Labeler - ABLE C&C CO., LTD. (689540284)

Registrant - ABLE C&C CO., LTD. (689540284)

Establishment				
Name	Address	ID/FEI	Business Operations	
ABLE C&C CO., LTD.		689540284	manufacture(13733-017)	

Revised: 10/2012 ABLE C&C CO., LTD.