SONATURAL POW DER4ROOM MAKEUP HOLDING FINISH POW DER FIXER BRIGHT PINK- dimethicone powder Sonatural Global 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: Dimethicone 2.0%

INACTIVE INGREDIENT

Inactive ingredients: Talc, Silica, Methyl Methacrylate Crosspolymer, Caprylic/Capric Triglyceride, Boron Nitride, Phenyl Trimethicone, Triethoxycaprylylsilane, Magnesium Stearate, Diisostearyl Malate, Caprylyl Glycol, Ethylhexylglycerin, CI 77491, Mica (CI 77019), 1,2-Hexanediol, Titanium Dioxide (CI 77891), CI 77499, Tocopheryl Acetate, Argania Spinosa Kernel Oil, Red 7, Methicone, Tin Oxide, Aloe Barbadensis Leaf Extract, Cocos Nucifera (Coconut) Oil

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: 1. If the following symptoms occur, discontinue use and consult a dermatologist: 1) Red spots, swelling, itchiness, or irritation upon use 2) If above symptoms occur when skin is in direct sunlight 2. Do not use on open wounds and on skin with eczema or dermatitis 3. Storage instructions: 1) Close lid tightly after each use 2) Keep out of reach of children 3) Store at room temperature away from direct sunlight

KEEP OUT OF REACH OF CHILDREN

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INDICATIONS & USAGE

Indications & Usage: Apply and pat lightly to the eye area before makeup, or sebaceous gland area after makeup with the puff.

DOSAGE & ADMINISTRATION

Dosage & Administration: Get appropriate amount onto puff and pat lightly and evenly over the eye or sebaceous gland area.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



SONATURAL POW DER4ROOM MAKEUP HOLDING FINISH POW DER FIXER BRIGHT PINK

dimethicone powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71322-050
Route of Administration	TOPICAL		
	TOPICAL	,	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	0.12 g in 6 g

Inactive Ingredients	
Ingredient Name	Strength
Talc (UNII: 7SEV7J4R1U)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	

	Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
l	1 NDC:71322-050-02	1 in 1 CARTON	03/02/2017		
l	1 NDC:71322-050-01	6 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 final	part347	03/02/2017	

Labeler - Sonatural Global Co.,Ltd (694818511)

Registrant - Sonatural Global Co.,Ltd (694818511)

Establishment			
Name	Address	ID/FEI	Business Operations
Sonatural Global Co.,Ltd		694818511	relabel(71322-050)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(71322-050)

Revised: 3/2017 Sonatural Global Co.,Ltd