

FASCY MOISTURE BOMB HAND PEACH 40ML- dimethicone cream
FASCY 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 Ingredient: Dimethicone 1.0%

INACTIVE INGREDIENT

Inactive Ingredients: Water, Glycerin, Cetearyl Alcohol, Mineral Oil, Dipropylene Glycol, Cyclopentasiloxane, Glyceryl Stearate, PEG-100 Stearate, Polysorbate 60, Sorbitan Stearate, Sodium Polyacrylate, Ethylhexyl Stearate, Xanthan Gum, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Adenosine, Potassium Hydroxide, Trideceth-6, Butyrospermum Parkii (Shea) Butter, Butylene Glycol, Panthenol, Allantoin, Aloe Barbadensis Leaf Extract, Prunus Persica (Peach) Fruit Extract, Ethylhexylglycerin, Disodium EDTA, Methylparaben, Propylparaben, Phenoxyethanol, CI 14700, CI 17200, Fragrance

PURPOSE

Purpose: Skin Protectant

WARNINGS

Warnings: For external use only. When using this product do not get into eyes, Stop use and ask a doctor if rash occurs. Do not use on - deep puncture wounds - animal bites - serious burns. Keep out of reach of children. Do not keep it in direct sunlight, high or low temperature.

KEEP OUT OF REACH OF CHILDREN

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How to use

How to use: Apply desired amount and massage into the hands.

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PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FASCY MOISTURE BOMB HAND CREAM PEACH 40ML

dimethicone cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70991-090

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	0.4 g in 40 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70991-090-02	1 in 1 CARTON	02/01/2017	
1	NDC:70991-090-01	40 mL in 1 TUBE; 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	02/01/2017	

Labeler - FASCY Co.,LTD. (689204222)

Registrant - FASCY Co.,LTD. (689204222)

Establishment

Name	Address	ID/FEI	Business Operations
FASCY Co.,LTD.		689204222	relabel(70991-090)

Establishment

Name	Address	ID/FEI	Business Operations
WELCOS CO.,LTD.		689131584	manufacture(70991-090)

Revised: 3/2017

FASCY Co.,LTD.