

FASCY MOISTURE BOMB HAND CRE AM MILK- 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, Panthenol, Butylene Glycol, Allantoin, Milk Protein Extract, 1,2-Hexanediol, Aloe Barbadosis Leaf Extract, Ethylhexylglycerin, Disodium EDTA, Methylparaben, Propylparaben, Phenoxyethanol, 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

KEEP OUT OF REACH OF CHILDREN

How to use

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

How to use

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

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FASCY MOISTURE BOMB HAND CRE AM MILK

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70991-040
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	Dimethicone	0.8 g in 80 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:70991-040-02	1 in 1 CARTON	08/01/2016	
1	NDC:70991-040-01	80 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	08/01/2016	

Labeler - FASCY Co.,LTD. (689204222)**Registrant** - FASCY Co.,LTD. (689204222)**Establishment**

Name	Address	ID/FEI	Business Operations
FASCY Co.,LTD.		689204222	repack(70991-040)

Establishment

Name	Address	ID/FEI	Business Operations
WELCOS CO.,LTD.		689131584	manufacture(70991-040)

Revised: 9/2016

FASCY Co.,LTD.