

BIOWHITE RESILIENT MASSAGE - dimethicone cream
ZION SYNTHETIC FIBER 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.

Drug Facts

Active ingredient: DIMETHICONE 4.50%

Inactive ingredients:

Water, Argania Spinosa Kernel Oil, Squalane, Simmondsia Chinensis (Jojoba) Seed Oil, Butyrospermum Parkii (Shea Butter), Beeswax, Cethyl Ethylhexanoate (CEH), Olea Europaea (Olive) Fruit Oil, Butylene Glycol, Macadamis Ternifolia Seed Oil, Glycerin, Limnanthes Alba (Meadowfoam) Seed Oil, Hydrolyzed Pea Protein, Lecithin, Phytosterols, Stearyl Alcohol, Polysorbate 60, Hydrogenated Coconut Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Juice Powder, Glyceryl Stearate, Glycine Soja (Soybean) Oil, Stearic Acid, Bisabolol, Triethanolamine, Sorbitan Sesquiolate, Phenoxyethanol, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sericin, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Methyl Paraben, Chaenomeles Sinensis Fruit Extract, Allantoin, Ceramide3, Hydrogenated Lecithin, Caprylic/Capric Triglyceride, Disodium EDTA, Xanthan Gum, Tourmaline, Aluminum Silicate, Topaz, Amethyst Powder, Zeolite, Sodium Hyaluronate, Sea Water, Butylated Hydroxytoluene (BHT), Flavor

Purpose: Skin Protectant

Warnings:

In case of having following symptoms after using this, you're advised to stop using it immediately.

If you keep using it, the symptoms will get worse and need to consult a dermatologist.

- In case of having problems such as red rash, swollenness, itching, stimulation during usage.

- In case of having the same symptoms above on the part you put this product on by direct sunlight.

You are banned to use it on the part where you have a scar, eczema, or dermatitis.

In case of getting it into your eyes, you have to wash it immediately.

Keep out of reach of children:

Keep out of reach of babies and children.

Indications and usage:

Tighten the lid after using it.

Don't keep it in the place where the temperature is extremely hot or low and exposed to the direct sunlight.

Use it in the evening after washing face.

Dosage and administration:

Apply after washing face.

Take a small amount of cream about 1.0g-1.5g onto the fingertips and gently massage over the entire face. (cheeks, nostrils, mouth corners, forehead, and the around of eyes, even your hands)

Blot face lightly with tissue, and may sleep without washing it.



BIOWHITE RESILIENT MASSAGE

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4478 1-210
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	4.27 g in 95 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ARGAN OIL (UNII: 4V59G5UW9X)	

SQUALANE (UNII: GW89575KF9)
JOJOBA OIL (UNII: 724GKU717M)
SHEA BUTTER (UNII: K49155WL9Y)
YELLOW WAX (UNII: 2ZA36H0S2V)
OLIVE OIL (UNII: 6UYK2W1W1E)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERIN (UNII: PDC6A3C0OX)
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
POLYSORBATE 60 (UNII: CAL22UVI4M)
HYDROGENATED COCONUT OIL (UNII: JY810XM10M)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
SOYBEAN OIL (UNII: 241ATL177A)
STEARIC ACID (UNII: 4ELV7Z65AP)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44781-210-01	95 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/01/2011	

Labeler - ZION SYNTHETIC FIBER CO., LTD. (688011147)

Registrant - ZION SYNTHETIC FIBER CO., LTD. (688011147)

Establishment

Name	Address	ID/FEI	Business Operations
ZION SYNTHETIC FIBER CO., LTD.		688011147	manufacture

Revised: 1/2012

ZION SYNTHETIC FIBER CO., LTD.