MIZON GOOD NIGHT WHITE SLEEPING MASK- dimethicone cream
MIZON 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, CYCLOMETHICONE, BUTYLENE GLYCOL, NIACINAMIDE, TREHALOSE, GLYCERIN, ALCOHOL, WATER (AND) SODIUM HYALURONATE, POLYSORBATE 20, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, TRIETHANOLMAINE, CARBOMER, WATER (AND) SCLEROTIUM GUM, BROUSSONETIA EXTRACT, MORUS ALBA BARK EXTRACT, PANTETHINE, PLACENTAL PROTEIN, NATTO GUM, BIOSCCHARIDE GUM-1, DISODIUM EDTA, METHYL PARABEN, PROPYL PARABEN, CI 17200, CI 42090, FRAGRANCE

PURPOSE

Purpose: Skin protectant and brightening

WARNINGS

Warnings: 1. If following symptoms occur, stop use and consult a doctor: red spots, swelling, itching, irritation, or symptoms where product has been applied under direct sunlight. 2. Do not use on scarred skin or if you have dermatitis or eczema. 3. Keep the cap closed on this product. 4. Keep away from direct sunlight or heat. 5. Keep out of reach of children.

KEEP OUT OF REACH OF CHILDREN

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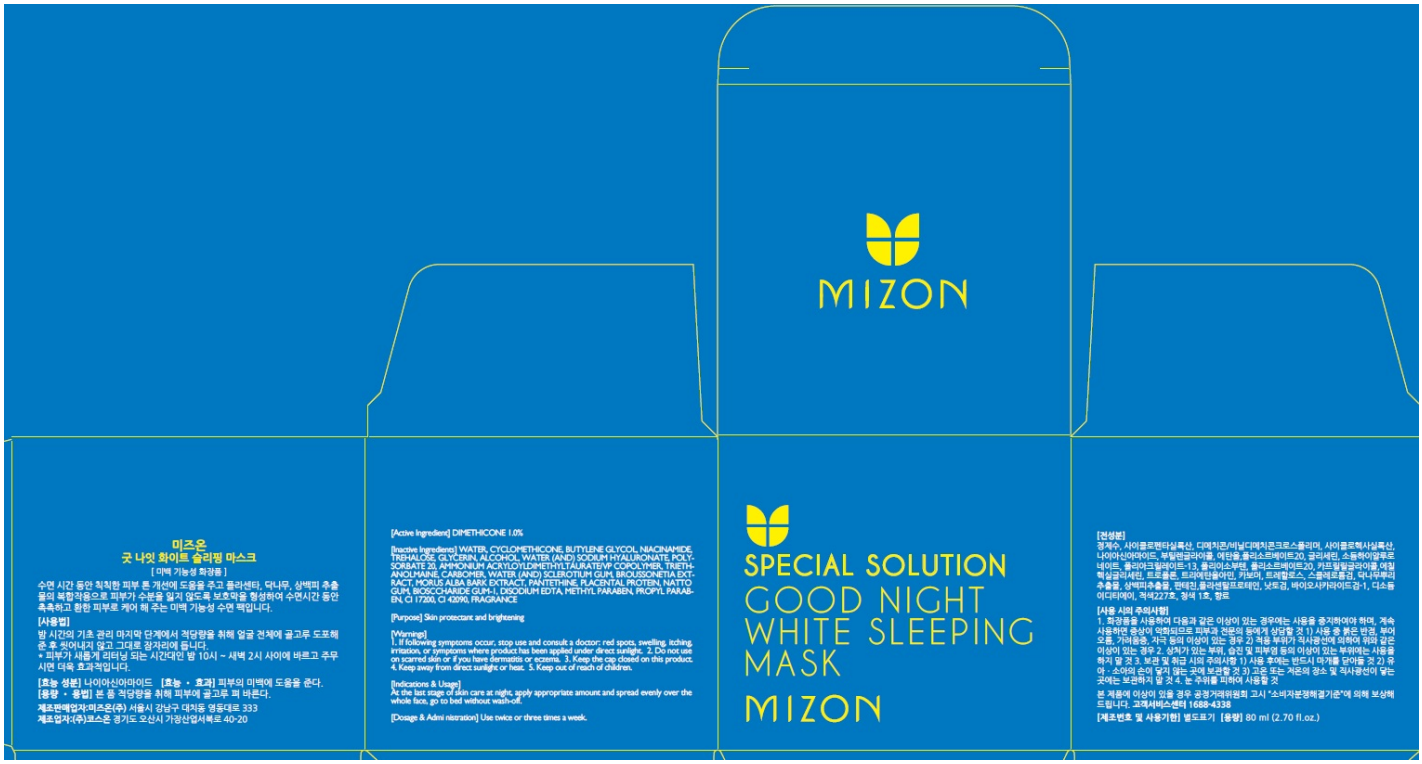
INDICATIONS & USAGE

Indications & Usage: At the last stage of skin care at night, apply appropriate amount and spread evenly over the whole face, go to bed without wash-off.

DOSAGE & ADMINISTRATION

Dosage & Administration: Use twice or three times a week.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MIZON GOOD NIGHT WHITE SLEEPING MASK

dimethicone cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57718-100
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)	
NIACINAMIDE (UNII: 25X51I8RD4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57718-100-01	80 mL in 1 CARTON; 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	03/02/2016	

Labeler - MIZON CO., LTD. (557815570)

Registrant - MIZON CO., LTD. (557815570)

Establishment

Name	Address	ID/FEI	Business Operations
MIZON CO., LTD.		557815570	repack(57718-100)

Establishment

Name	Address	ID/FEI	Business Operations
Coson Co., Ltd.		689835593	manufacture(57718-100)

Revised: 3/2016 MIZON CO., LTD.