

GYEOL- dimethicone shampoo
MayimHayyim Bio 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

glycerin

water, butylene glycol, etc.

skin protectant

keep out of reach of the children

apply masks to clean face

leave the mask on your face about 20 minutes until it begins to dry

1. Do not use in the following cases (Eczema and scalp wounds)

2. Side Effects

1) Due to the use of this drug if rash, irritation, itching and symptoms of hypersensitivity occur discontinue use and consult your pharmacist or doctor

3. General Precautions

1) If in contact with the eyes, wash out thoroughly with water. If the symptoms are severe, seek medical advice immediately

2) This product is for external use only. Do not use for internal use

4. Storage and handling precautions

1) If possible, avoid direct sunlight and store in cool and area of low humidity

2) In order to maintain the quality of the product and avoid misuse

3) Avoid placing the product near fire and store out of reach of children

for external use only

How to use:

- Before pumping, shake the shampoo bottle 10 – 15 times up and down
- Apply the shampoo liquid to scalp and hair, and wait for 1-2 minutes
- Thoroughly rinse off with water to remove shampoo liquid residue from scalp

Caution on Use

- Wash off immediately when contracted into eye.
- Do not use on wounds or any areas subject to eczema and skin diseases.
- In the event of any troubles incurred from using the product, stop using it and consult with the dermatologist as the keeping on using of product may deteriorate the symptom.
 - Event of troubles such as red spot, swelling, itching or irritation are incurred during the use.
 - Event of troubles described above due to the direct sunlight on applied area.
- If not completely washed off after use, it may cause loss of hair or discoloration. Please wash off completely after use of product.
- Caution on Handling and Storage
 - Make sure to close the cap after use.
 - Keep the product at places not accessible by the hands of babies and children.
 - Do not keep the product at places subject to high or low heat and direct sunlight.

GYEOL

dimethicone shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70354-0001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.6 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70354-0001-1	300 mL in 1 BOTTLE; 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	12/18/2015	

Labeler - MayimHayyim Bio Co., ltd. (689041078)

Registrant - MayimHayyim Bio Co., ltd. (689041078)

Establishment

Name	Address	ID/FEI	Business Operations
MayimHayyim Bio Co., ltd.		689036771	manufacture(70354-0001)

Revised: 12/2015

MayimHayyim Bio Co., ltd.