

AQUATO BABY- dimethicone cream ItoB 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.

Dimethicone

Water, Glycerin, Butylene Glycol, etc

Skin Protectant - Moisturizing, Soothing

keep out or reach of the children

Dispense the right amount and gently apply onto entire face in accordance with the skin texture.

Allow product to be absorbed by skin.

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

2.Side Effects

1)Due to the use of this druf if rash, irritation, itching and symptoms of hypersnesitivity occur diconinue use and consult your phamacisr or doctor

3.General Precautions

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

2)This product is for exeternal 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 in reach of children

for external use only



AQUATO BABY

dimethicone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71567-0001 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 1 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|------------------------------------|-----------------|
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:71567-0001-1 | 80 mL in 1 JAR; Type 0: Not a Combination Product | 07/05/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC monograph final | part347 | 07/05/2017 | |

Labeler - ItoB Co.,Ltd (690099724)

Registrant - ItoB Co.,Ltd (690099724)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|----------------|---------------|----------------------------|
| TAENAM MEDICOS CO., LTD | | 689846359 | manufacture(71567-0001) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|----------------|---------------|--------------------------------------|
| ItoB Co.,Ltd | | 690099724 | pack(71567-0001) , label(71567-0001) |