

DR.ALTHEA HYDRATION BOOSTING SERUM- dimethicone cream

Dr. Althea

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

DIMETHICONE

SQUALANE, HYDROLYZED HYALURONIC ACID, ALGAE EXTRACT, WATER, BUTYLENE GLYCOL, ETC

Helps Hydrate skin

keep out of reach of the children

After using a skin toner, apply this product to skin and spread it over skin evenly once or twice every morning and night.

1. If the following symptoms occur after product use, stop using the product immediately and consult a dermatologist (continuous use can exacerbate the symptoms).

1) Occurrence of red spots, swelling, itchiness, and other skin irritation

2) If the symptoms above occur after the application area is exposed to direct sunlight

2. Do not use on open wounds, eczema, and other skin irritations

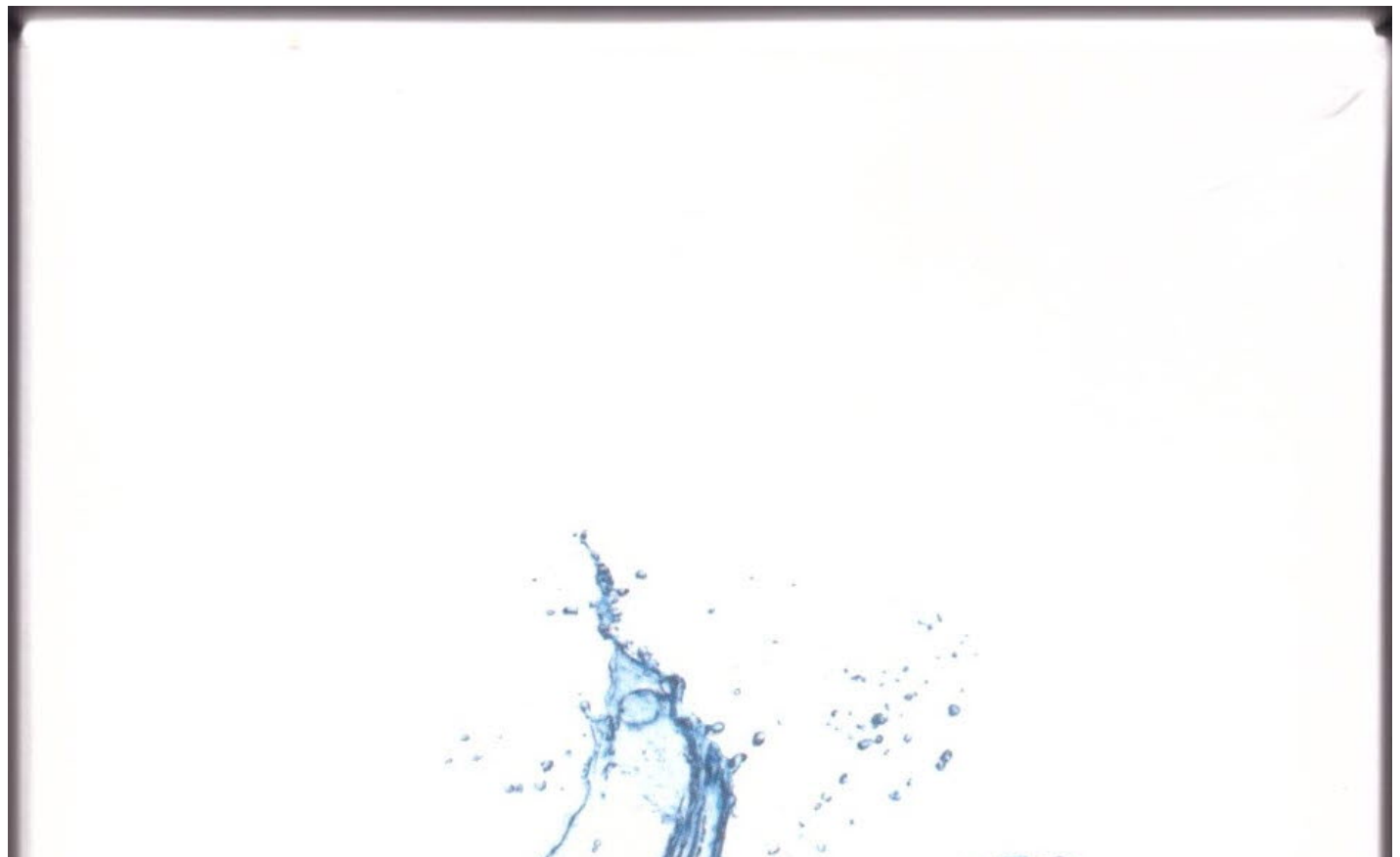
3. Precaution for Storage and Handling

1) Close the lid after use

2) Keep out of reach of infants and children

3) Do not store in a place with high/low temperature and exposed to direct sunlight

for external use only





Dr. Althea

Hydration Boosting Serum

Squalane · Hydrolyzed hyaluronic acid · Algae Extract

— **Everyday Hydrating Formula** —

50ml / 1.69 fl.oz.

DR.ALTHEA HYDRATION BOOSTING SERUM

dimethicone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70905-0003 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 2 g in 100 mL |

Inactive Ingredients

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70905-0003-1 | 50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 08/11/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 08/11/2016 | |

Labeler - Dr. Althea (689694436)

Registrant - Dr. Althea (689694436)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------|---------|-----------|-------------------------|
| Dr. Althea | | 689694436 | manufacture(70905-0003) |