DR.ALTHEA TO BE EYECONIC EYE 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

WATER, CYCLOPENTASILOXANE, BUTYLENE GLYCOL, GLYCERIN, TOCOPHEROL, ETC.

Skin Protectant

keep out of reach of the children

Take appropriate amount of eye serum evenly spread on the skin

- 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 to store in a place with high/low temperature and exposed to direct sunlight

for external use only



DR.ALTHEA TO BE EYECONIC EYE SERUM

dimethicone cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70905-0010

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	DIMETHICO NE (UNII: 92RU3N3Y10) (DIMETHICO NE - UNII:92RU3N3Y10)	DIMETHICONE	6.0192 g in 100 mL

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		

Packaging

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1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:70905- 0010-1	1 in 1 PACKAGE	08/11/2016	
	1	20 mL in 1 BOTTLE, WITH APPLICATOR; 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	08/11/2016	

Labeler - Dr. Althea (689694436)

Registrant - Dr. Althea (689694436)

Establishment

Listabiliment				
Name	Address	ID/FEI	Business Operations	
Dr. Althea		689694436	manufacture(70905-0010)	

Revised: 10/2016 Dr. Althea