## ULTRA SOOTHING FORMULA- dimethicone cream Dermafirm INC.

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.

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#### **Drug Facts**

Dimethicone

Water, Beeswax, etc

Skin Protectant - Soothing, Moisturizing

keep out of reach of the children

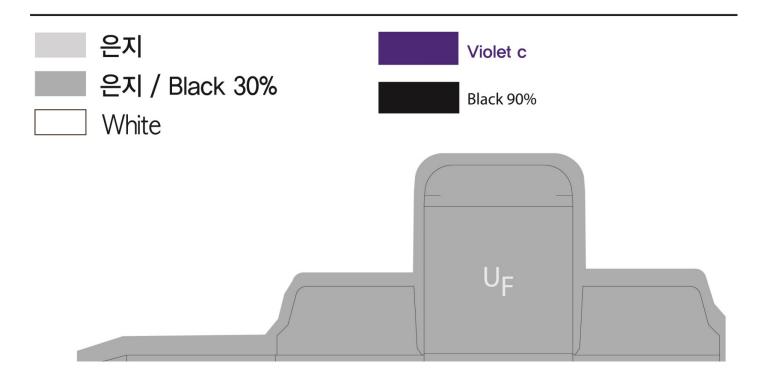
After using toner, apply this lotion on your face.

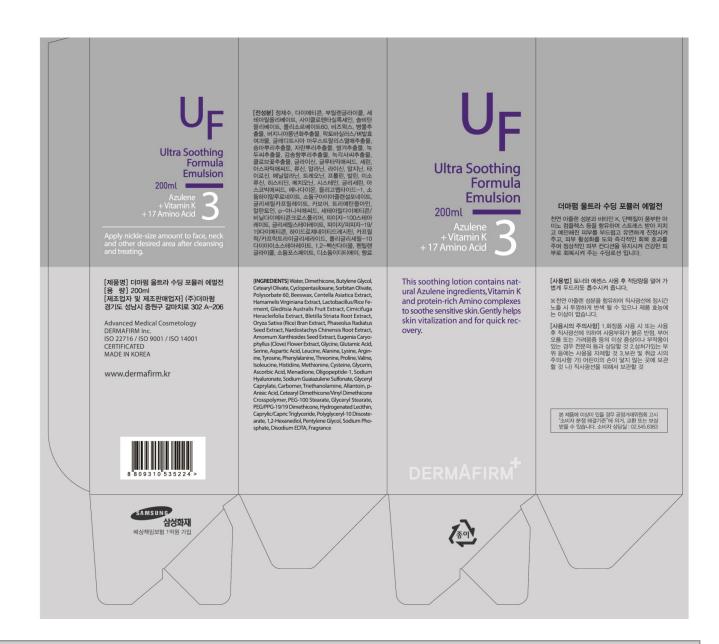
Gently spread and tap.

- 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 symptopms of hypersnesitivity occur dicontinue use and consult your phamacisr or doctor
- 3.General Precautions
- 1)If in contact with the eyes, wash out thoroughty 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

# 울트라 수딩 포뮬러 에멀전 200ml 단상자





#### ULTRA SOOTHING FORMULA

dimethicone cream

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:71638-0009 Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	7 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
YELLOW WAX (UNII: 2ZA36H0S2V)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:71638-0009-	200 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/02/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/02/2018	

## Labeler - Dermafirm INC. (690171603)

### Registrant - Dermafirm INC. (690171603)

Establishment			
Name	Address	ID/FEI	Business Operations
Dermafirm INC.		690171603	label(71638-0009), pack(71638-0009), manufacture(71638-0009)

Revised: 4/2018 Dermafirm INC.