ULTRA SOOTHING TONER- allantoin liquid
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.

Drug Facts

Allantoin

Water, Glycerin

Skin protectant

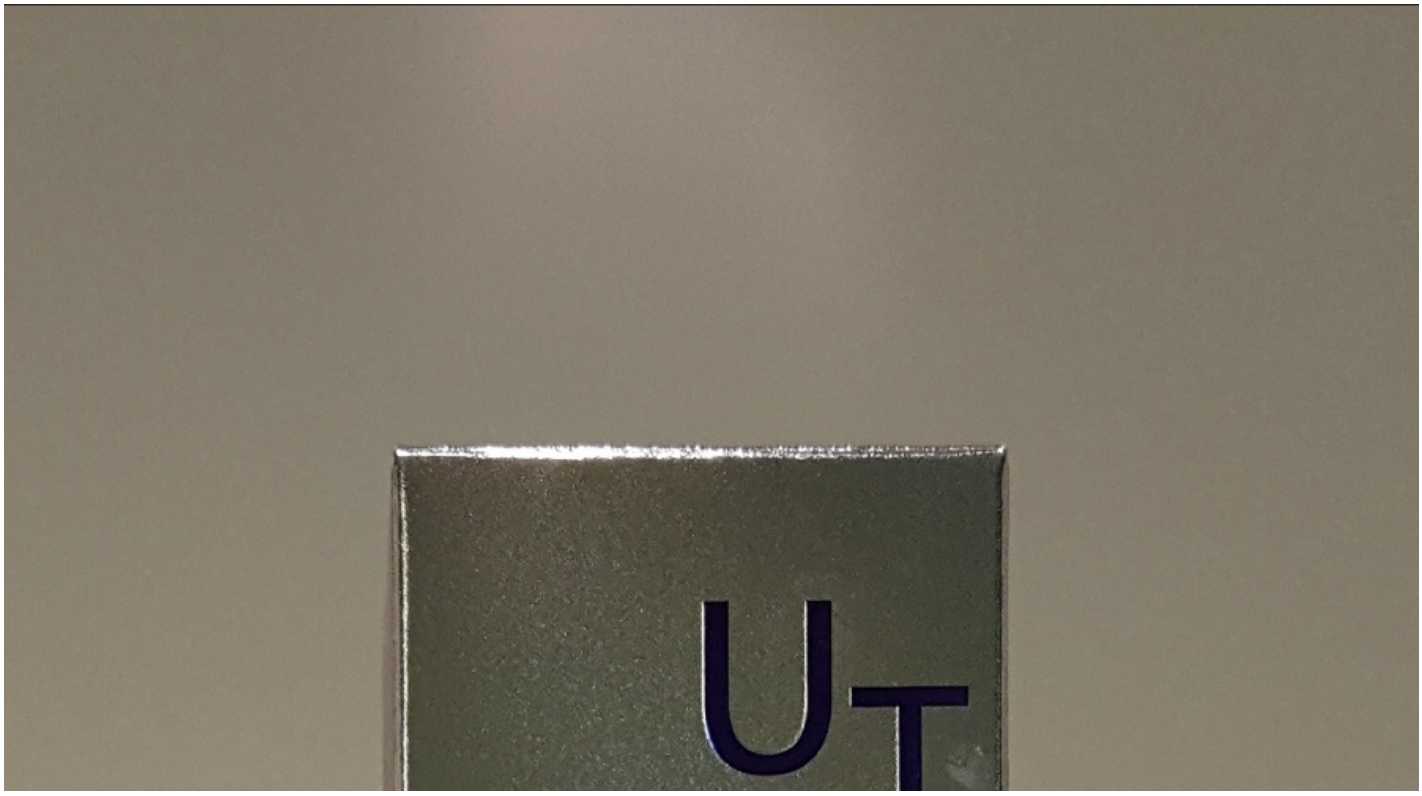
Soothing

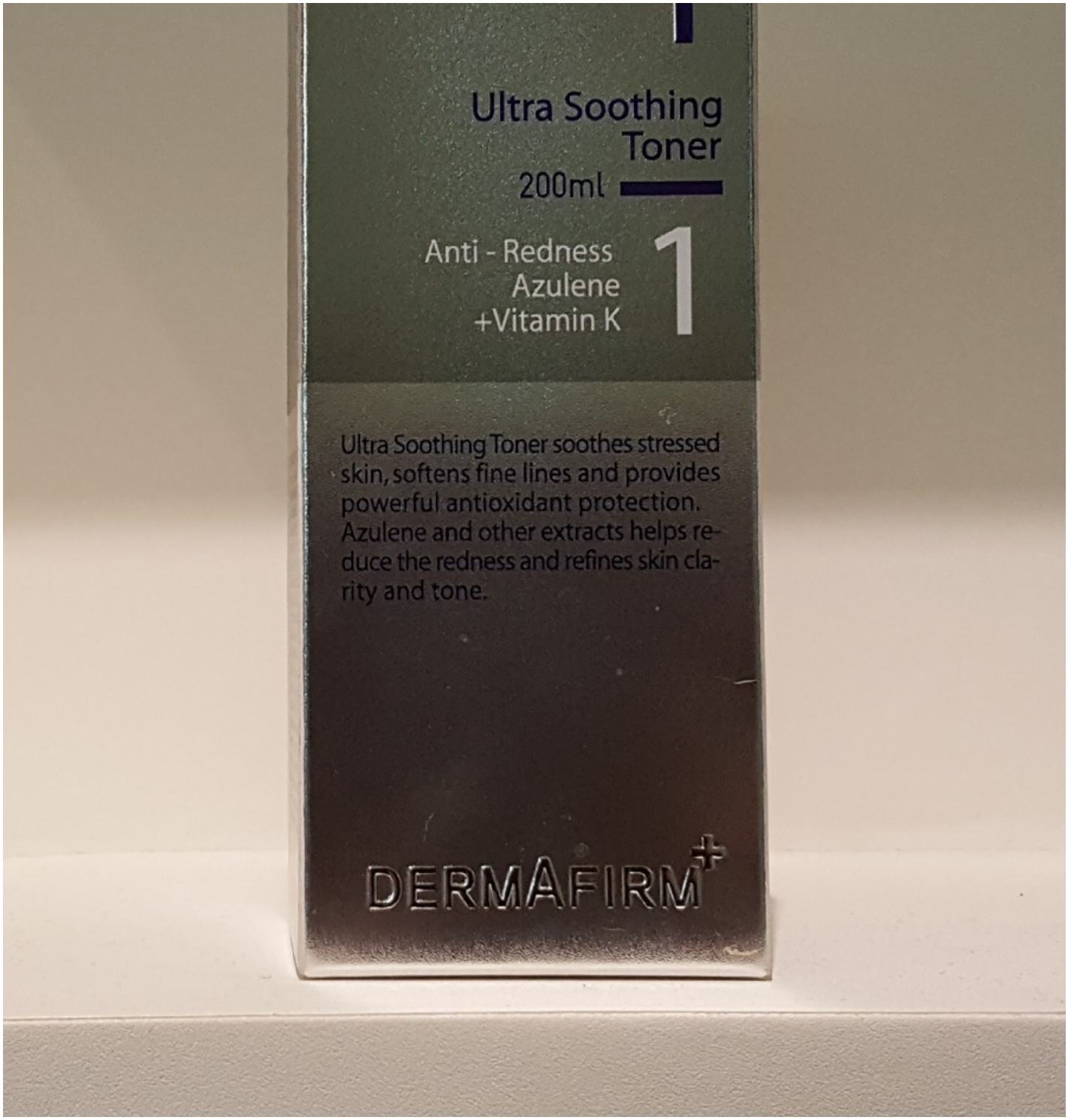
keep out of reach of the children

After cleansing, soak it in a cotton swab and use it as if you wipe it out carefully.

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





ULTRA SOOTHING TONER

allantoin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71638-0008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71638-0008-1	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	09/04/2017	

Labeler - Dermafirm INC. (690171603)

Registrant - Dermafirm INC. (690171603)

Establishment

Name	Address	ID/FEI	Business Operations
Dermafirm INC.		690171603	label(71638-0008) , pack(71638-0008) , manufacture(71638-0008)

Revised: 9/2017 Dermafirm INC.