UREA 40- urea gel SSG Ventures Inc

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Urea 40



DIRECTIONS:
APPLY TO AFFECTED AREA AT LEAST TWICE DAILY OR AS NEEDED.

ACTIVE INGREDIENTS:

UREA 40% INACTIVE INGREDIENTS:

PRESERVED WATER, MINERAL OIL, PROPYLENE GLYCOL, TRIETHANOLAMINE, COCONUT OIL, EMULTHIX, CARBOMER, XANTHAN GUM, TEA TREE OIL, ALOE VERA, METHYLPARABEN, PROPYLPARABEN

SAFETY WARNING:

FOR EXTERNAL USE ONLY. AVOID CONTACT TO EYES.
KEEP OUT OF REACH OF CHILDREN. STOP USE AND
CONSULT DOCTOR IF CONDITION WORSENS OR
CLEARS UP AND REOCCURS.

KEEP LID FIRMLY CLOSED. STORE IN COOL DRY PLACE.

ACTIVE INGREDIENTS:

UREA 40%

SOOTHES ROUGH & DRY SKIN

HEALS CORNS & CALLOUSES

SOOTHES ROUGH & DRY SKIN

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KEEP LID FIRMLY CLOSED. STORE IN COOL DRY PLACE.

KEEP OUT OF REACH OF CHILDREN.

APPLY TO AFFECTED AREA AT LEAST TWICE DAILY OR AS NEEDED.USE CONTINUOUSLY FOR 2-3 WEEKS FOR OPTIMAL RESULTS.

PRESERVED WATER, MINERAL OIL, PROPYLENE GLYCOL, TRIETHANOLAMINE, COCONUT OIL, EMULTHIX, CARBOMER, XANTHAM GUM, TEA TREE OIL, ALOE VERA, METHYLPARABEN, PROPYLPARABEN

KEEP LID FIRMLY CLOSED, STORE IN COOL DRY PLACE.

ENHANCED WITH TEA TREE OIL & ALOE VERA

APPLY TO AFFECTED AREA AT LEAST TWICE DAILY OR AS NEEDED.USE CONTINUOUSLY FOR 2-3 WEEKS FOR OPTIMAL RESULTS.

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UREA 40

urea gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81376-211

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	4 g in 10 mL	

Inactive Ingredients			
Ingredient Name	Strength		
METHYLPARABEN (UNII: A2I8C7HI9T)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
XANTHAN GUM (UNII: TTV12P4NEE)			
MINERAL OIL (UNII: T5L8T28FGP)			
COCONUT OIL (UNII: Q9L0O73W7L)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 903K93S3TK)			
TEA TREE OIL (UNII: VIF565UC2G)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			

Product Characteristics			
Color	white (Opaque White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:81376- 211-01	113 mL in 1 JAR; Type 0: Not a Combination Product	04/01/2021	
	2	NDC:81376- 211-03	226 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	04/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2021	
		04/01/2021	

Labeler - SSG Ventures Inc (047626115)

Establishment				
Name	Address	ID/FEI	Business Operations	
SSG Ventures Inc		047626115	manufacture(81376-211)	

Revised: 4/2021 SSG Ventures Inc