UREA 40 PLUS HA- urea gel
Scientific Solutions Global LLC

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.

ACTIVE INGREDIENTS:

UREA

SOOTHES ROUGH & DRY SKIN

HEALS CORNS & CALLOUSES

SOFTENS NAILS

SOOTHES ROUGH & DRY SKIN

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.

KEEP OUT OF REACH OF CHILDREN.

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

ALOE VERA, CARBOMER, COCONUT OIL, EMULSIFIERS, GREEN TEA, MINERAL OIL, PRESERVED WATER, POPYLENE GLYCOL, SODIUM HYALURONATE, TEA TREE OIL, TRIETHANOLOAMINE, XANTHAM GUM

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.

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

UREA 40 PLUS HA

urea gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71718-213
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	40 g in 113 g

Inactive Ingredients

Ingredient Name	Strength
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
WATER (UNII: 059QF0KO0R)	
TRIDECETH-10 (UNII: G624N6MSBA)	
TEA TREE OIL (UNII: VIF565UC2G)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71718-213-01	113 g in 1 JAR; Type 0: Not a Combination Product	09/20/2019	
2	NDC:71718-213-02	113 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/20/2019	
3	NDC:71718-213-03	226 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	09/26/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/20/2019	

Labeler - Scientific Solutions Global LLC (097291290)

Establishment

Name	Address	ID/FEI	Business Operations
Scientific Solutions Global LLC		097291290	manufacture(71718-213)