

**UREA 20- urea gel
AvPAK**

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 20% Cream

Active Ingredient: UREA 20%

Purpose: Moisturizer

Usage: Soothes, Softens and Moisturizes Dry Rough Skin.

WARNINGS SECTION

Caution: Do not apply to broken skin. If redness occurs, discontinue use. Avoid contact with eyes.

KEEP OUT OF REACH OF CHILDREN. For External Use Only.

Do not use: Do not use if safety seal on the tube is broken or missing. For lot number and exp. date, see crimp of tube or carton.

Directions: Apply to desired areas of the hands, feet, knees, or elbows twice daily, or as directed by a physician. Rub into the skin until fully absorbed. Do not use on tender skin areas such as the face, neck, or scalp.

Stop use: Do not apply to broken skin. If redness occurs, discontinue use. Avoid contact with eyes.

Inactive Ingredients: Cetyl Alcohol, Carbomer, Glycerin, Glyceryl Stearate SE, Mineral Oil, Purified Water, Stearyl Alcohol, Triacetin, White Petrolatum.

Storage: Store at 20°C (68°F - 77°F), excursions permitted between 15°C and 30°C (59°F - 86°F). Protect from Freezing. Store in a cool dry place. [See USP Controlled Room Temperature]

Questions or comments? 1-855-361-3993

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

UREA 20% Cream

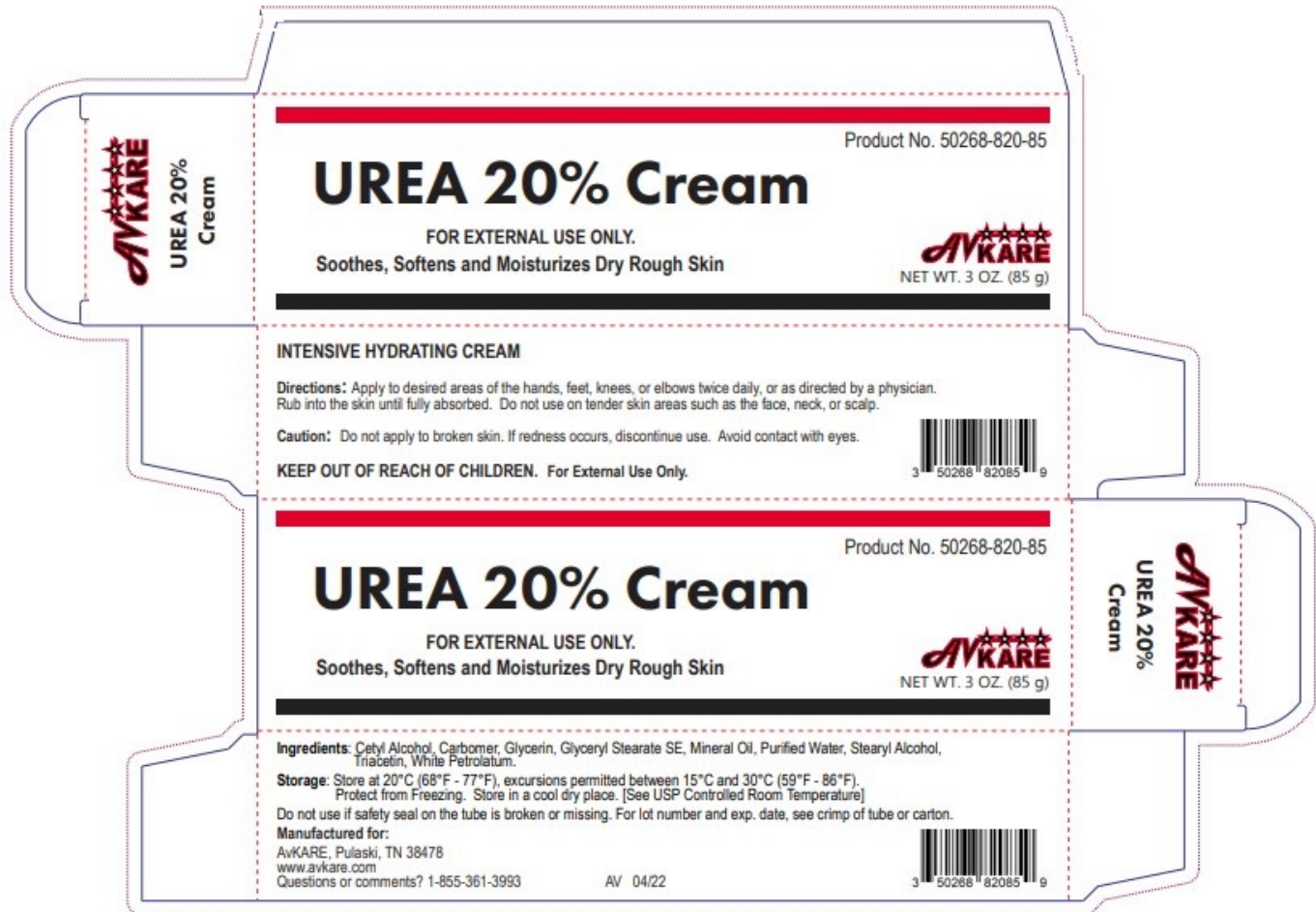
FOR EXTERNAL USE ONLY.

Soothes, Softens and Moisturizes Dry Rough Skin

AvKARE

NET WT. 3 OZ. (85 g)

Manufactured for: AvKARE,
Pulaski, TN 38478
www.avkare.com
Questions or comments? 1-855-361-3993 AV 04/22



UREA 20% Cream

Product No. 50268-820-85

FOR EXTERNAL USE ONLY.

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Manufactured for:

AvKARE
Pulaski, TN 38478
www.avkare.com
AV 01/22



UREA 20

urea gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50268-820
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	

WHITE PETROLATUM (UNII: B6E5W8RQJ4)

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:50268-820-85	1 in 1 CARTON	09/19/2022	
1		85 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/19/2022	

Labeler - AvPAK (832926666)

Revised: 3/2024

AvPAK