

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

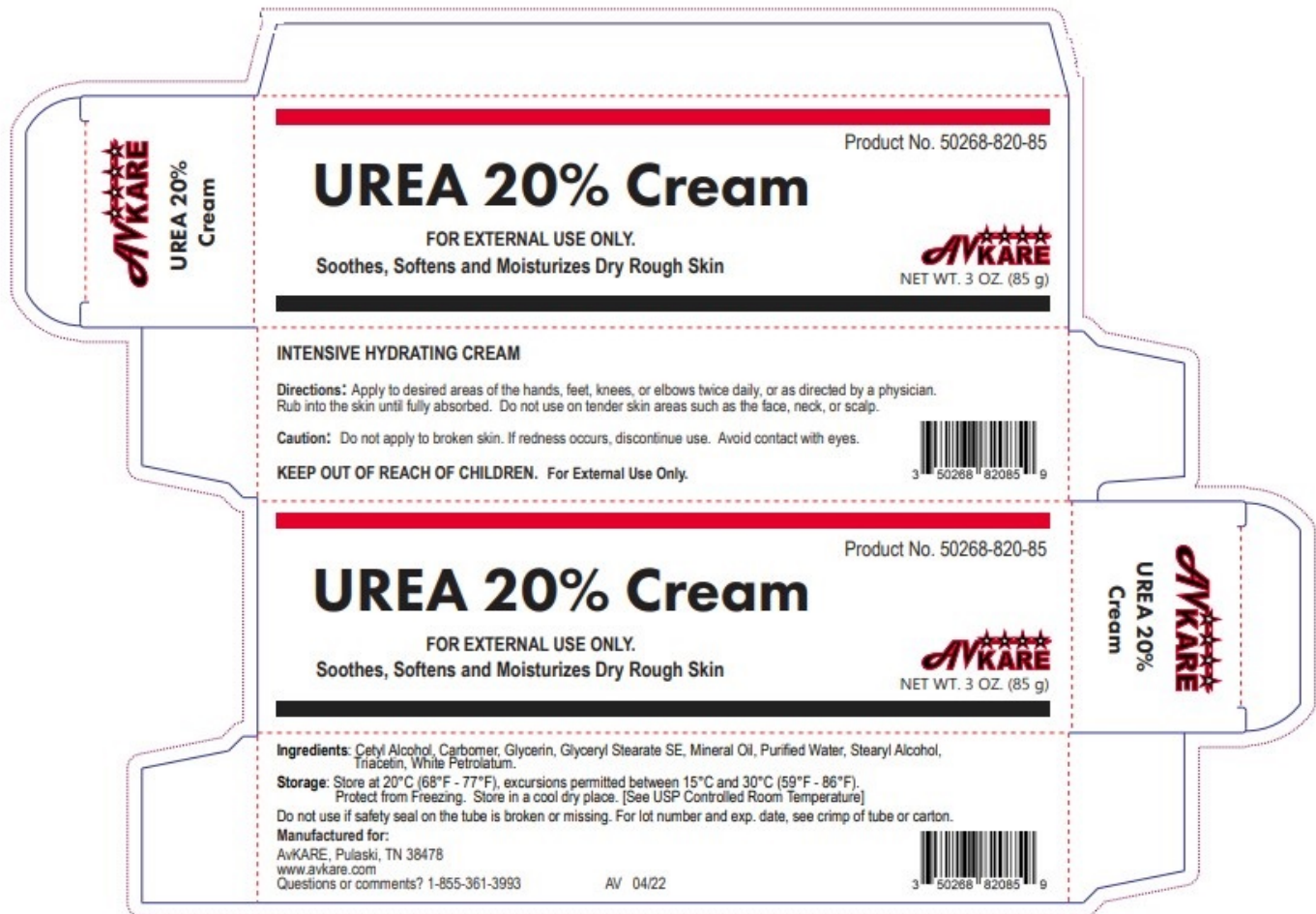
FOR EXTERNAL USE ONLY.

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

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Manufactured for:

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



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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
CETYL ALCOHOL (UNII: 936JST6JCN)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
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: 9/2022

AvPAK