UREMOL 20% CREAM- urea cream
Odan Laboratories Ltd

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.

Uremol 20% Cream

Active ingredient

Urea 20%

Inactive ingredients

Caprylic, Caprilic triglyceride, carbomer 940, ceteareth-12, ceteareth-20, citrid acid, diazolidinyl urea, glyceryl monostearate, methylparaben, octyldodecanol, potassium phosphate monobasic, propylene glycol, propylparaben, purified water, sodium phosphate dibasic,

Indications

Uremol helps relieve the symptoms of dry thickened skin conditions such as itchthyosis and xerosis. Directions-adult, apply up to two times per day on clean dry skin.Do not use on irritated or dammaged skin.Clean hands properly after application. Stop use if condition worsens.

Purpose

Uremol 20% helps relieve the symptoms of dry thickened skin conditions such as itchthyosis and xerosis.

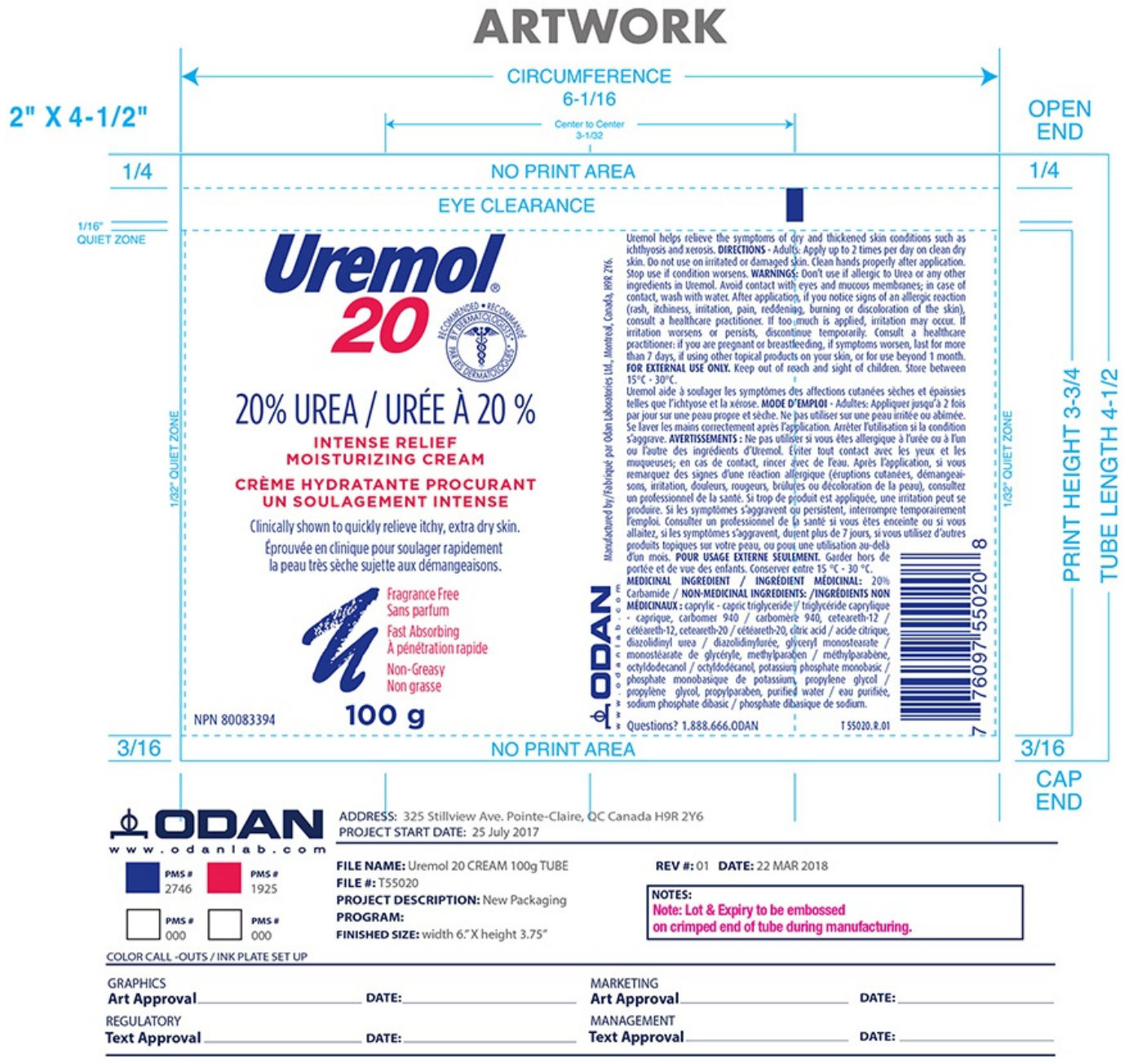
Dosage and Administration

Uremol 20%- Directions-adult, apply up to two times per day on clean dry skin.Do not use on irritated or dammaged skin. Store between 15-30 ^{0}C.

Warning

Don't use if allergic to urea or any other ingredients in Uremol. Avoid contact with eyes and mucous membrane; in case of contact, wash with water. After application, if you may notice rash, itchiness, irritation, pain, reddening, burning or discoloration of the skin, consult a healthcare practitioner. If too much is applied, irritation may occur. If irritation worsens or persists, discontinue temporarily. Consult a health care professional: if you are pregnant or breastfeeding, if symtoms worsen or last for more than 7 days or if using other topical product on your skin or for use beyond 1 month.

For external use only. Keep out of reach and sight of children.



UREMOL 20% CREAM

urea cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61344-455
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
WATER (UNII: 059QF0KO0R)	
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)	
CAPRYLIC ACID (UNII: OBL58JN025)	
TRICAPRIN (UNII: O1PB8EU98M)	
CETEARETH-12 (UNII: 7V4MR24V5P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61344-455-25	100 g in 1 TUBE; Type 6: Drug/Biologic Combination	05/31/2019	
2	NDC:61344-455-50	225 g in 1 TUBE; Type 6: Drug/Biologic Combination	05/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/31/2019	

Labeler - Odan Laboratories Ltd (208585604)

Establishment

Name	Address	ID/FEI	Business Operations
Odan Laboratories LTD		208585604	manufacture(61344-455)

Revised: 11/2023 Odan Laboratories Ltd