

**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.*

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**Uremol 20% Cream**

**Active ingredient**

Urea 20%

**Inactive ingredients**

Caprylic, Caprilic triglyceride, carbomer 940, cetareth-12, cetareth-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 damaged 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 damaged skin. Store between 15-30 °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 symptoms 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.

1/2" 1/4 1/32" QUIET ZONE 3/16

CIRCUMFERENCE 6-1/16 Center to Center 3-1/32

NO PRINT AREA

EYE CLEARANCE

OPEN END

1/4

1/32" QUIET ZONE

PRINT HEIGHT 3-3/4

TUBE LENGTH 4-1/2

3/16

CAP END

Uremol®  
20

20% UREA / URÉE À 20 %

INTENSE RELIEF  
MOISTURIZING CREAM

CRÈME HYDRATANTE PROCURANT  
UN SOULAGEMENT INTENSE

Clinically shown to quickly relieve itchy, extra dry skin.  
Éprouvée en clinique pour soulager rapidement  
la peau très sèche sujette aux démangeaisons.

100 g

FRAGRANCE FREE  
SANS PARFUM  
FAST ABSORBING  
À PÉNÉTRATION RAPIDE  
NON-GREASY  
NON GRASSE

NPN 80083394

ODAN

Questions? 1.888.666.ODAN

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155020.R.01

ADDRESS: 325 Stillview Ave. Pointe-Claire, QC Canada H9R 2Y6  
PROJECT START DATE: 25 July 2017

FILE NAME: Uremol 20 CREAM 100g TUBE  
FILE #: T55020  
PROJECT DESCRIPTION: New Packaging  
PROGRAM:  
FINISHED SIZE: width 6" X height 3.75"

REV #: 01 DATE: 22 MAR 2018

NOTES:  
Note: Lot & Expiry to be embossed  
on crimped end of tube during manufacturing.

COLOR CALL-OUTS / INK PLATE SET UP

GRAPHICS  
Art Approval  
REGULATORY  
Text Approval

DATE:

MARKETING  
Art Approval  
MANAGEMENT  
Text Approval

DATE:

# 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: YRC528SWJY)				
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)