

**UREMOL- urea lotion**  
**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 10% Lotion**

**Active ingredient**

Urea 10%

**Inactive ingredients**

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

**Indication and usage**

Uremol temporarily protects and helps relieve minor skin irritation and itching. Apply to skin up to 3 times/day. Do not use under 2 years old, unless directed by a physician. Used on children should be supervised by an adult. Stop use if condition worsens.

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For external use only. Keep out of reach and sight of children. Store between 15-30 °C.

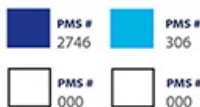
**Warning**

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 you may notice rash, itchiness, irritation, pain, reddening, burning or discoloration of the skin, which could be sign of an allergic reaction. Stinging may occur if applied to damaged skin. If too much is applied, irritation may occur. If irritation worsens or persists, discontinue temporarily. Consult a health care professional if symptoms worsen or last for more than 7 days or if using other topical product on your skin.

# ARTWORK



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



FILE NAME: Uremol 10 LOTION 250ml BOTTLE  
FILE #: B55110  
PROJECT DESCRIPTION: New Packaging  
PROGRAM:  
FINISHED SIZE: width 2.588" X height 4.35"

REV #: 01 DATE: 28 August 2017

NOTES:

COLOR CALL-OUTS / INK PLATE SET UP

GRAPHICS  
Art Approval Eric Bell DATE: 28 August 2017  
REGULATORY  
Text Approval \_\_\_\_\_ DATE: \_\_\_\_\_

MARKETING  
Art Approval \_\_\_\_\_ DATE: \_\_\_\_\_  
MANAGEMENT  
Text Approval \_\_\_\_\_ DATE: \_\_\_\_\_

## UREMOL

urea lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61344-452
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)			UREA	100 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 94255I6E2T)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)				
TRICAPRILIN (UNII: 6P92858988)				
CARBOMER 940 (UNII: 4Q93RCW27E)				
CETEARETH-12 (UNII: 7V4MR24V5P)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)				
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
XANTHAN GUM (UNII: TTV12P4NEE)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
OCTYLDODECANOL (UNII: 461N1O614Y)				
Product Characteristics				
Color			Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61344-452-30	250 mL in 1 BOTTLE; Type 6: Drug/Biologic Combination	05/31/2019	

# ARTWORK



**ODAN**  
www.odanlab.com

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## 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(61344-452)

Revised: 12/2022

Odan Laboratories Ltd