

GORDONS UREA 40 - urea ointment

Gordon Laboratories

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.

GORDONS UREA 40

Urea 40% has been used for many years for the nonsurgical avulsion of mycotic nails. Nonsurgical avulsion is a conservative procedure which can be utilized by the geriatric, diabetic or vascular patient. Nonsurgical avulsion has the advantage of avoiding the possible side effects of oral drugs.

Gordon's Urea 40% is supplied as 1 oz. Jars.

Urea 40%, Petrolatum 17.8%, White Wax 5%, Anhydrous Lanolin 15%, Purified Water

For loosening, debriding and avulsion of devitalized nail tissue. Apply to affected area in an apertured pad. Protect surrounding skin. Apply Urea 40% to the diseased nail surface and cover with plastic film. Anchor with adhesive tape. Cover with "finger cut" of plastic or vinyl glove and anchor with more adhesive tape. Keep dry and occlusive for 3-7 days. Cleanse, debride and reapply if necessary.

Hypersensitivity to Urea or any of the components of this preparation. If redness or irritation occurs, discontinue use. For external use only. Keep out of reach of children.

Urea is an organic compound present in mammals. Wehn it was first synthesized from an inorganic compound in the last century. Urea is now prepared by heating Calcium Cyanamide with water under pressure. Proteolytic action on the nail plate and nail bed by its keratolytic properties, with the resulting maceration inducing an effective, painless and bloodless nail removal procedure.

CAUTION: If redness or irritation occurs, discontinue use.

Federal Law Prohibits Dispensing Without a Prescription.

INDICATIONS: For loosening, debriding and avulsion of devitalized nail tissue.

FOR EXTERNAL USE ONLY
Keep Out of Reach Of Children

NDC 10481-3005-1

GORDON'S UREA 40%

FOR PROFESSIONAL USE ONLY

Gordon

Laboratories

NET WT. 1 OZ.
Gordon Laboratories • Upper Darby, PA 19082 USA

INGREDIENTS: Urea 40% in a specially formulated petrolatum base.

DIRECTIONS: Apply to affected area in an apertured pad. Protect surrounding skin. Apply Urea 40% to the diseased nail surface and cover with plastic film. Anchor with adhesive tape. Cover with a "finger" cut of plastic or vinyl glove and anchor with more adhesive tape. **KEEP DRY AND OCCLUSIVE FOR 3-7 DAYS.** Cleanse debride and reapply if necessary.

Lot#
Exp.

GORDONS UREA 40

urea ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:10481-3005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Urea (UNII: 8W8T17847W) (Urea - UNII:8W8T17847W)	Urea	0.4 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
PETROLATUM (UNII: 4T6H12BN9U)	
LANOLIN (UNII: 7EV65EAW6H)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10481-3005-1	30 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/16/2010	

Labeler - Gordon Laboratories (002333847)**Registrant** - Gordon Laboratories (002333847)**Establishment**

Name	Address	ID/FEI	Business Operations
Gordon Laboratories		002333847	manufacture

Revised: 7/2010

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