UREA- urea gel
Exact-Rx, Inc.

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 Nail Gel 45%

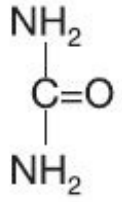
(in a vehicle containing camphor, menthol and eucalyptus oil)

Rx Only

For external use only. Not for ophthalmic use.
Keep away from eyes, lips and mucous membranes.

DESCRIPTION: UREA Nail Gel 45%is a keratolytic emollient, which is a gentle, yet potent, tissue softener for nails and/or skin. Each gram of **UREA Nail Gel 45%**contains 45% Urea, camphor, edetate disodium, eucalyptus oil, hydroxyethyl cellulose, menthol, propylene glycol and purified water.

UREA is a diamide of carbonic acid with the following chemical structure:



CLINICAL PHARMACOLOGY: Urea gently dissolves the intracellular matrix, which results in loosening the horny layer of skin and shedding scaly skin at regular intervals, thereby softening hyperkeratotic areas. Urea also hydrates and gently dissolves the intercellular matrix of the nail plate, which can result in the softening and eventual

debridement of the nail plate.

PHARMACOKINETICS: The mechanism of action of topically applied Urea is not yet known.

INDICATIONS AND USES: For debridement and promotion of normal healing of hyperkeratotic surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris or eschar. Urea is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, corns and calluses, as well as damaged and ingrown nails.

CONTRAINDICATIONS: Known hypersensitivity to any of the listed ingredients.

WARNINGS: For external use only. Avoid contact with eyes, lips or mucous membranes.

PRECAUTIONS: This medication is to be used as directed by a physician and should not be used to treat any condition other than that for which it was prescribed. If redness or irritation occurs, discontinue use. **KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.**

PREGNANCY: Pregnancy Category B. Animal reproduction studies have revealed no evidence of harm to fetus, however, there are no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, **Urea Nail Gel 45%**should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS: It is not known whether or not this drug is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when **Urea Nail Gel 45%**is administered to a nursing woman.

ADVERSE REACTIONS: Transient stinging, burning, itching or irritation may occur and normally disappear on discontinuing the medication.

Call your doctor for medical advice about side effects.

DOSAGE AND ADMINISTRATION: Apply **Urea Nail Gel 45%**to diseased or damaged nail tissue twice per day, or as directed by a physician.

DIRECTIONS FOR SKIN: Apply **Urea Nail Gel 45%**to affected area(s) twice per day, or as directed by a physician. Rub in until gel is absorbed.

HOW SUPPLIED:

Urea Nail Gel 45% is supplied in a 28 mL glass bottle NDC 42808-0204-28.

Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from freezing.

Manufactured in the U.S.A. for Exact-Rx, Inc., Melville, NY 11747

00-0204-28-205-00

Iss:7/11

PRINCIPAL DISPLAY PANEL

For External Use Only

NDC 42808-0204-28 Rx Only

Urea
In a vehicle containing
menthol, camphor &
eucalyptus oil

45%

NAIL GEL

Exact-Rx.
INCORPORATED

Net Wt. 28 mL

For External Use Only

Urea
NAIL GEL
45%

For External Use Only

CAUTION: If redness or irritation occurs, discontinue use.

Each gram contains 45% Urea, camphor, carbomer, eucalyptus oil, glycerin, menthol, purified water, sodium hydroxide, triacetin.

KEEP OUT OF REACH OF CHILDREN. In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

Store at controlled room temperature 15 to 30°C (59 to 86°F). Protect from freezing.

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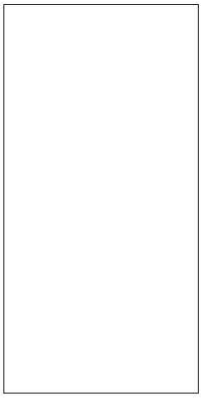

NDC 42808-0204-28 Rx Only

Urea
In a vehicle containing menthol, camphor & eucalyptus oil

45%

NAIL GEL

FOR EXTERNAL USE ONLY. NOT FOR OPTHALMIC USE. KEEP AWAY FROM EYES, LIPS AND MUCOUS MEMBRANES

Urea Nail Gel 45% is indicated for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyologist, eczema, keratosis, keratoderma, corns and calluses, as well as damaged, devitalized and ingrown nails.

DIRECTIONS: Apply to affected area(s) twice per day, or as directed by a physician. Rub in until gel is absorbed. See package insert for full prescribing information.

Exact-Rx

Net Wt. 28 mL

00-0204-28-101-02

342808204281

UREA

urea gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42808-204
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	450 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
EUCALYPTUS OIL (UNII: 2R04ONI662)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42808-204-28	1 in 1 CARTON	08/01/2011	
1		28 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)

Revised: 10/2023 Exact-Rx, Inc.