XUREA- urea cream
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

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.

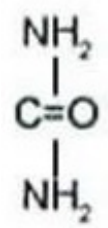
Xurea

Xurea (Urea 39% Cream) Rx only
For Topical Dermatological Use Only
Rx Only - Caution: Federal Law restricts this product to sale by, or on the order of a licensed healthcare practitioner.

Xurea Description

Xurea Cream is a potent keratolytic emollient which is a gentle, yet potent, tissue softener for skin and/or nails.
Each gram of Xurea Cream contains:
ACTIVE: 39% Urea in a cream base of:
INACTIVES: Aqua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Propylene Glycol, Dimethicone, Melaleuca Alternifolia (Tea Tree) Oil, Helianthus Annuus (Sunflower) Oil, Chamomilla Recutita (Chamomile) Extract, Carbomer, Triethanolamine, Phenoxyethanol, Ethylhexylglycerin.

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



Xurea - Clinical Pharmacology

Urea gently dissolves the intercellular 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 prurient 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, ingrown

and devitalized nails.

Contraindications

Xurea Cream is contraindicated in patients with known hypersensitivity to any of the listed ingredients.

Warnings

For external use only. Avoid contact with eyes, lips or mucous membranes. Do not use on areas of broken skin.

Precautions

Stop use and ask a doctor if redness or irritation develops. After applying this medication, wash hands and unaffected areas thoroughly. If swallowed, get medical help or contact Poison Control Center right away. KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

PREGNANCY

Pregnancy Category B

Animal reproduction studies have revealed no evidence of harm to the fetus, however, there are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, **Xurea** Cream 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 **Xurea** Cream is administered to a nursing woman.

Adverse Reactions

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

Xurea - Dosage and Administration

Apply **Xurea** Cream to affected skin two to three times per day as needed or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail tissue two to three times per day or as directed by a physician. Best applied to affected areas immediately after showering and just before bedtime.

How is Xurea Supplied

Xurea (39% Urea Cream) is supplied in:

8oz (227gm) Jar NDC 72678-034-01

Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59° - 86°F). Protect from freezing. [See USP Controlled Room Temperature.]

Manufactured for:
NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY

Branchburg, NJ 08876

Rx only

PRINCIPAL DISPLAY PANEL - 227 gm Jar Label

Rx only

NDC 72678-034-01

Xurea UREA 39% CREAM

Smooth - Spreadable - Moisturizing

Xurea’s high amount of urea exhibits intensive keratolyic and peeling effects. Thoroughly nourishes, helping to prevent cracks, and drying of your skin.

FOR TOPICAL USE ONLY

Net WT. 8OZ (227 gm)

Packaging

Rx Only 72678-034-01

Xurea

UREA 39% CREAM

Smooth - Spreadable - Moisturizing

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FOR TOPICAL USE ONLY Net WT. 8oz (227g)

Ingredients

Active Ingredient	**Purpose**
Urea 39%	Moisturizer

Ingredients: Aqua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Propylene Glycol, Dimethicone, Melaleuca Alternifolia (Tea Tree) Oil, Helianthus Annuus (Sunflower) Oil, Chamomilla Recutita (Chamomile) Extract, Carbomer, Triethanolamine, Phenoxyethanol, Ethylhexylglycerin.

Indications: Debrides rough patches and dead skin while moisturizing living tissue and rehydrating derma to a healthy appearance.

Dosage & Administration

Directions: Apply up to 2 to 3 times per day as needed to dry skin areas. Best applied to affected areas immediately after showering and just before bedtime.

Warnings: Should signs of irritation develop, discontinue use. Not for ophthalmic use. Keep away from eyes, lips and mucous membranes. Do not use on open wounds, cracked, or bleeding skin. For external use only.

KEEP OUT OF REACH OF CHILDREN
If swallowed, get medical help or contact poison control center immediately.

Storage: Store at Room Temperature.

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Manufactured For:

NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY
Branchburg, NJ 08876

XUREA

urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72678-034
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	390 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CHAMOMILE (UNII: FGL3685T2X)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72678-034-01	227 g in 1 JAR; Type 0: Not a Combination Product	09/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/19/2019	

Labeler - NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY (967054623)

Revised: 10/2019 NATIONAL BIO GREEN SCIENCES LIMITED LIABILITY COMPANY