UREA- urea cream
Bryant Ranch Prepack

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 40% Cream

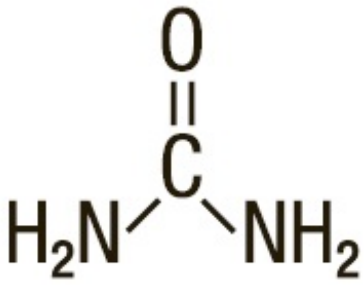
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram contains 400 mg of urea in a vehicle consisting of: carbomer, cetyl alcohol, dimethyl isosorbide, glyceryl stearate, mineral oil, petrolatum, propylene glycol, purified water, sodium hydroxide and xanthan gum.

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



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 of the skin.

Pharmacokinetics: The mechanism of action of topically applied urea is not yet known.

INDICATIONS:

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 pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.

CONTRAINDICATIONS:

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

WARNING:

KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS:

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

General: This product 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 and consult a physician.

Information for Patients: Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. Avoid contact with eyes, lips and mucous membranes.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also have not been performed.

Pregnancy:*Category C.*Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

ADVERSE REACTIONS:

Transient stinging, burning, itching or irritation may occur and normally disappear upon discontinuing the use of this product.

DOSAGE AND ADMINISTRATION:

Apply to affected area(s) twice per day or as directed by a physician. Rub in until completely absorbed.

Apply to diseased or damaged nail(s) twice per day, or as directed by a physician.

STORAGE:

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. Keep bottle tightly closed.

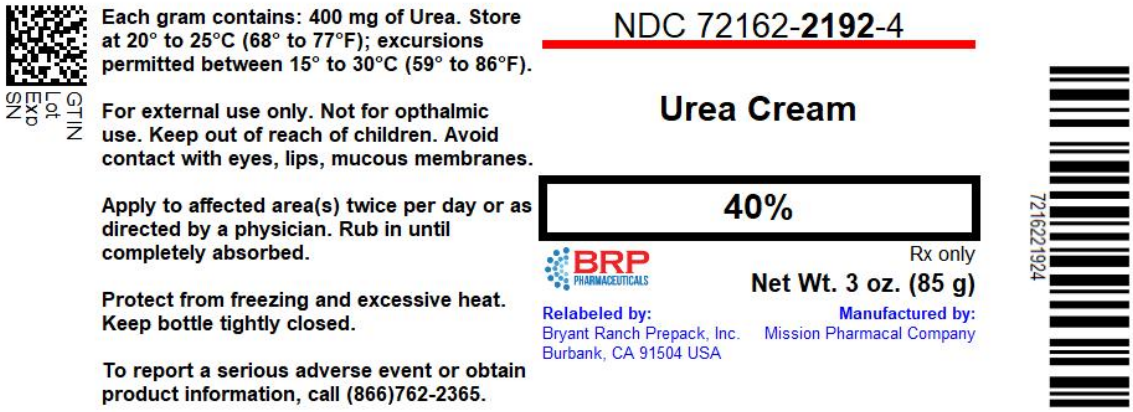
HOW SUPPLIED:

7 oz. (198.4 g) bottles, NDC 72162-2192-2
3 oz. (85 g) bottles, NDC 72162-2192-4
1 oz. (28.35 g) bottles, NDC 72162-2192-7

To report a serious adverse event or obtain product information, call (866) 762-2365.

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Urea 40% Cream



UREA
urea cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72162-2192(NDC:44523-617)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	400 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72162-2192-2	198.4 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	
2	NDC:72162-2192-4	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	
3	NDC:72162-2192-7	28.35 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/15/2018	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(72162-2192) , RELABEL(72162-2192)