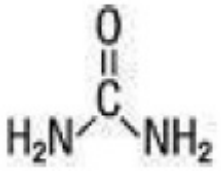
NOT APPLICABLE- protexa cream
Sterling-Knight Pharmaceuticals, LLC

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.

Protexa
Urea 42% CreamRx Only FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Protexa Cream (42% Urea) is a keratolytic emollient which is gentle, yet potent, tissue softener for nails and/or skin. Each gram contains 42% Urea, Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Glycerin, Ceteary Alcohol, Polysorbate 60, Dimethicone, C12-15 Alkyl Benzoate, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Aloe Barbadensis Leaf Juice Powder, Phenoxyethanol, Ethylhexylglycerin, Xanthan Gum, Citric Acid. Urea 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 AND USAGE:

This product is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, xerosis, ichthyosis, skin cracks and fissures, dermatitis, eczema, psoriasis, keratoses and calluses.

CONTRAINDICATIONS:

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

WARNINGS:

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.
CALL YOUR DOCTOR ABOUT SIDE EFFECTS.
Call your doctor about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

DOSAGE AND ADMINISTRATION:

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

HOW SUPPLIED:

Protexa Cream (42% Urea) is available as follows: 45g container, NDC 69336-810-45

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on the therapeutic equivalence.

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

Distributed By:
Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

Item: 810 Rev. 09/19

Protexa Urea 42% Cream - Label

NDC 69336-810-45

PROTEXA

Urea Cream 42%

For External Use Only.
Not for Ophthalmic Use.

NET WT. 45 g

Rx Only

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

Protexa 42% is indicated for the treatment of hyperkaratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, keratoderma, corns and calluses, as well as damaged, devitalized and ingrown nails.

DIRECTIONS: Apply cream to affected area(s). Rub in until cream is completely absorbed. Use only as directed by a physician. See package insert for full prescribing information.

CAUTION: If redness or irritation occurs, discontinue use.

Each gram contains: 42% Urea, Water, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Glycerin, Ceteary Alcohol, Polysorbate 60, Dimethicone, C12-15 Alkyl Benzoate, Glyceryl Stearate, PEG-100 Stearate, Propylene Glycol, Aloe Barbadensis Leaf Juice Powder, Phenoxyethanol, Ethylhexylglycerin, Xanthan Gum, Citric Acid.

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

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

Sterling | Knight PHARMACEUTICALS

Manufactured in the USA for
Sterling | Knight Pharmaceuticals, LLC
Ripley, MS 38663

Rev 1019-01
Item #810

N 3 69336 81045 6

Protexa Urea 42% Cream - Carton

NOT APPLICABLE

protexa cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69336-810
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Urea (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	Urea	42 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Water (UNII: 059QF0KO0R)	
ALMOND OIL (UNII: 66YXD4DKO9)	
GLYCERIN (UNII: PDC6A3C0OX)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Dimethicone (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 Stearate (UNII: YD01N1999R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Aloe (UNII: V5VD430YW9)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Xanthan Gum (UNII: TTV12P4NEE)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69336-810-45	1 in 1 CARTON	02/18/2020	
1		45 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/18/2020	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)

Establishment

Name	Address	ID/FEI	Business Operations

Sterling-Knight Pharmaceuticals, LLC		079556942	manufacture(69336-810) , label(69336-810)

Revised: 2/2020 Sterling-Knight Pharmaceuticals, LLC