

UMECTA MOUSSE UREA - urea foam aerosol, foam
Innocutis Holdings 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](#).

Umecta Mousse PI

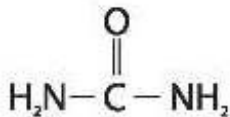
Description

Rx only

For topical use only

Not for ophthalmic use

Umecta is a keratolytic, emollient which is a gentle, yet potent, tissue softener for nails and skin. Each gram of Umecta mousse contains urea (40%), Butane, Butyrospermum Parkii (Shea Butter) Extract, Carbomer, Glycine Soya (Soy Bean) Sterol, Helianthus Annuus (Sunflower) Oil, Isobutane, Laureth-4, Polysorbate-20, Propane, Purified Water, Stearic Acid, Triethanolamine. 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. 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 Usage

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, ingrown

and devitalized nails.

Contraindications

Known hypersensitivity to any of the listed ingredients.

Warnings

For external use only. Avoid contact with eyes, lips or mucous membranes. Umecta Mousse canister - contents under pressure do not puncture or incinerate. Do not store at temperatures above 120° F.

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.

Pregnancy

Animal reproduction studies have not been conducted with Umecta. It is also not known whether Umecta can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Umecta 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 Umecta is administered to a nursing woman.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Adverse Reactions

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

Dosage and Administration

Apply Umecta PD bioadhesive emulsion/topical suspension or Umecta mousse to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed

How Supplied

Umecta (urea, 40%) mousse is available in a: 4 oz. can NDC 68712-020-01

Store at controlled room temperature 15-30°C (59-86°F).

Protect from freezing.

Manufactured for:

Innocutis Holdings LLC

Charleston, SC 29401

Toll Free: 1-800-499-4468

www.innocutis.com

www.umecta.com

NDC 68712-020-01



Dosage and Administration:

Apply Umecta® mousse to affected skin twice per day, or as directed by a physician. Rub in until completely absorbed. Apply to diseased or damaged nail tissue twice per day, or as directed by a physician.



Firmly push back nozzle until seal is broken. Maintain mousse can in an upright position when pushing the nozzle to dispense.



Do not turn can upside down.

Ingredients:

Active Ingredients: Urea 40%
 Inactive Ingredients: Butane, Butyrospermum Parkii (Shea Butter) Extract, Carbomer, Glycine Soya (Soy Bean) Sterol, Helianthus Annuus (Sunflower) Oil, Isobutane, Laureth-4, Polysorbate-20, Propane, Purified Water, Stearic Acid, Triethanolamine



WARNING:

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Manufactured for:
 Innocutis Holdings, LLC
 Charleston, SC 29401
 Toll Free: 1-800-499-4488
www.innocutis.com
www.Umecta.com

Rx Only
 For Topical Use Only
 Not For Ophthalmic Use

Net Wt 4 oz (113.4 g)



U.S. Pat. Nos.: 7,682,507; 7,605,676

UMECTA MOUSSE UREA

urea foam aerosol, foam

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68712-020
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
BUTANE (UNII: 6LV4FOR43R)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARBOMER 934 (UNII: Z135WT9208)	
SOYBEAN OIL (UNII: 241ATL177A)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ISOBUTANE (UNII: BXR49TP611)	

LAURETH-4 (UNII: 6HQ855798J)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPANE (UNII: T75W9911L6)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68712-020-01	113.4 g in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/01/2007	

Labeler - Innocutis Holdings LLC (071501252)

Establishment

Name	Address	ID/FEI	Business Operations
American Spraytech LLC		137135237	manufacture

Revised: 12/2011

Innocutis Holdings LLC