UMECTA MOUSSE UREA - urea foam aerosol, foam
EPI Health, Inc

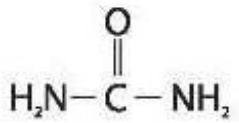
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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 120º 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 Monthers

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

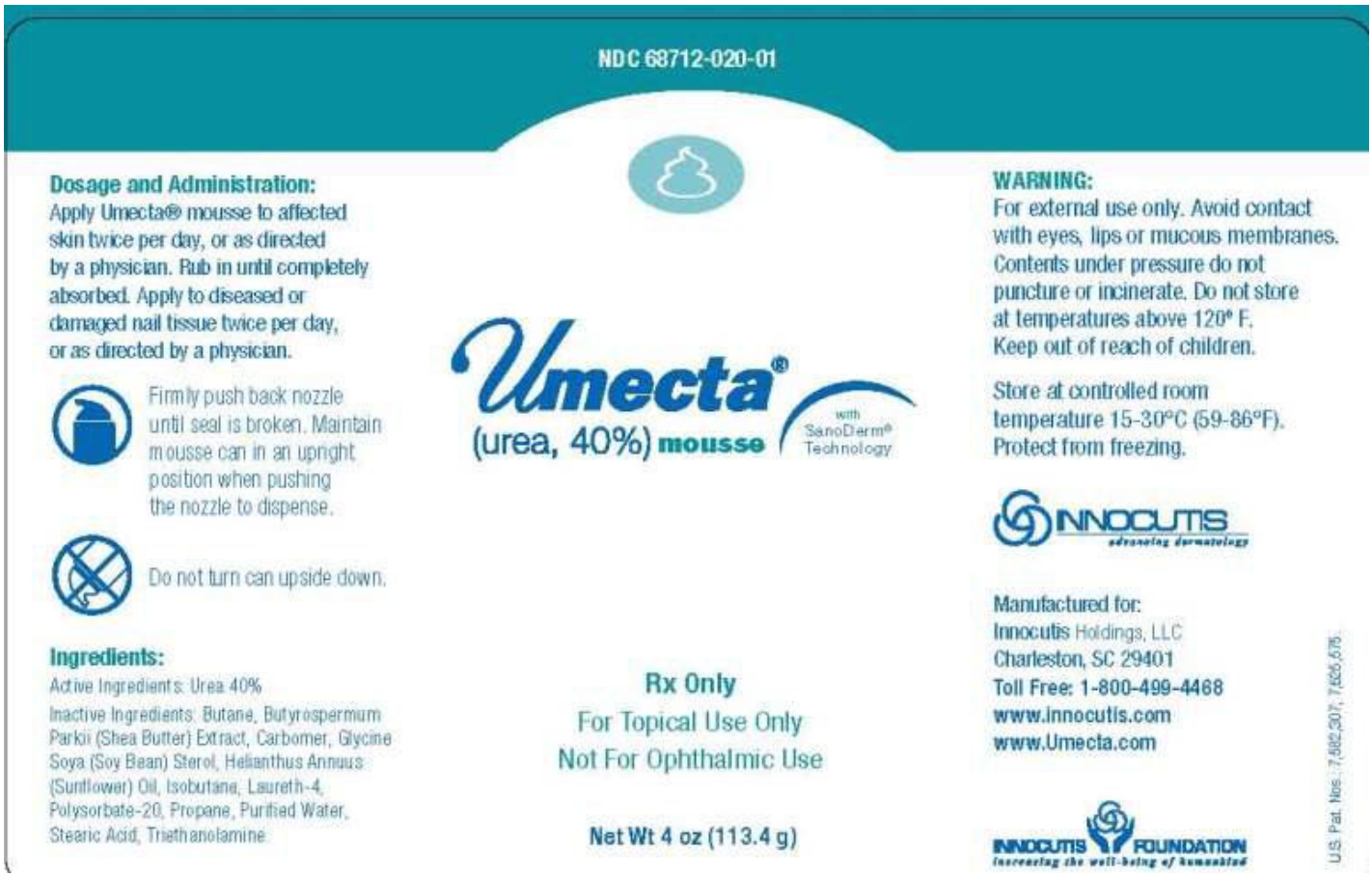
Umecta (urea, 40%) mousse is available in a: 4 oz. can NDC 68712-020-01

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



UMECTA MOUSSE UREA

urea foam aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71403-020
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 HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (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:71403-020-01	113.4 g in 1 CAN; Type 0: Not a Combination Product	09/01/2007	

Marketing Information

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

Labeler - EPI Health, Inc (080638894)

Establishment

Name	Address	ID/FEI	Business Operations
EPI Health, Inc		080638894	manufacture(71403-020)

Revised: 12/2017 EPI Health, Inc