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:

\[ \text{H}_2\text{N} - \text{C} - \text{NH}_2 \]

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
UMECTA MOUSSE  UREA
urea foam aerosol, foam

Product Information

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<th>Item Code (Source)</th>
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Active Ingredient/Active Moiety

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<td>UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)</td>
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Inactive Ingredients

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<td>BUTANE (UNII: 6LV4FOR43R)</td>
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<td>SHEA BUTTER (UNII: K49155WL9Y)</td>
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<td>CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)</td>
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<td>SOYBEAN OIL (UNII: 241ATL177A)</td>
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SUNFLOWER OIL (UNII: 3W1JG795YI)
ISO BUTANE (UNII: BXR49TP611)
LAURETH-4 (UNII: 6HQ855798J)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
PROPANE (UNII: T75W9911L6)
WATER (UNII: 059QF0KO0R)
STEARIC ACID (UNII: 4ELV7Z65AP)
TROLAMINE (UNII: 9O3K93S3TK)

Package |
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Marketing Information

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Labeler - EPI Health, Inc (080638894)

Establishment

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Revised: 12/2017