

# Umecta<sup>®</sup> (urea, 40%)

- Umecta PD™ (urea, 40% - sodium hyaluronate 0.3%) bioadhesive emulsion
- Umecta PD™ (urea, 40% - sodium hyaluronate 0.3%) bioadhesive topical suspension
- Umecta<sup>®</sup> 40% Nail Film (urea, 40%) suspension with applicator
- Umecta<sup>®</sup> 40% Nail Film (urea, 40%) suspension with pen applicator
- Umecta<sup>®</sup> (urea, 40%) mousse

**For topical use only. Not for ophthalmic use.**  
**Rx only.**

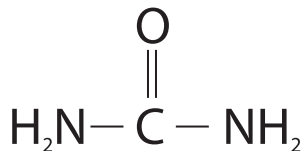
**Description:** Umecta<sup>®</sup> is a keratolytic, emollient which is a gentle, yet potent, tissue softener for nails and skin.

Each gram of Umecta PD™ bioadhesive emulsion and topical suspension contains 40% urea, sodium hyaluronate 0.3%, BHT, butyrospermum parkii fruit oil, citric acid, dimethylacrylamide (and acrylic acid (and) polystyrene ethyl methacrylate copolymer, disodium EDTA, glyceryl stearate, glycine soja sterol, helianthus annuus oil, hydroxypropylmethyl cellulose, purified water, sodium citrate, stearic acid.

Each gram of Umecta<sup>®</sup> 40% Nail Film suspension with applicator and pen applicator contains urea (40%), disodium EDTA, glycerin, hydroxyethylcellulose, PEG-6 caprylic/capric glycerides, purified water, and xanthan gum.

Each gram of Umecta<sup>®</sup> 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 Uses:** 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.

**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 Category C:** Animal reproduction studies have not been conducted with Umecta<sup>®</sup>. It is also not known whether Umecta<sup>®</sup> can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Umecta<sup>®</sup> 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<sup>®</sup> 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

**Emulsion/topical suspension/mousse:** Apply Umecta PD™ bioadhesive emulsion/topical suspension or Umecta<sup>®</sup> 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.

**40% Nail Film suspension:** Apply Umecta<sup>®</sup> 40% Nail Film suspension to diseased or damaged nail tissue or skin twice per day, or as directed by a physician. Cover with adhesive bandage or gauze, secure with adhesive tape. An additional option is to remove a "finger" from a plastic or vinyl glove and slip it over the bandage-covered site. Secure glove finger with additional adhesive tape.

## How Supplied:

Umecta PD™ (urea, 40% - sodium hyaluronate 0.3%) bioadhesive emulsion is available in a:  
7 oz. plastic tube  
NDC 68712-017-02

Umecta PD™ (urea, 40% - sodium hyaluronate 0.3%) bioadhesive topical suspension is available in a:  
9 oz. bottle  
NDC 68712-018-02

Umecta<sup>®</sup> (urea, 40%) 40% Nail Film suspension is available in a:  
18 ml bottle - with applicator  
NDC 68712-010-01

Box of 6 - 3 ml - pen applicators  
NDC 68712-010-03

Umecta<sup>®</sup> (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:  
JSJ Pharmaceuticals  
Charleston, SC 29401  
**Toll Free: 1-800-499-4468**  
**www.jsjpharm.com**  
**www.Umecta.com**



U.S. Pat. No.: 5,942,243

August 2008