**DERMASORB XM COMPLETE KIT- urea cream with moisturizing cream**
**Crown Laboratories**

*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.*

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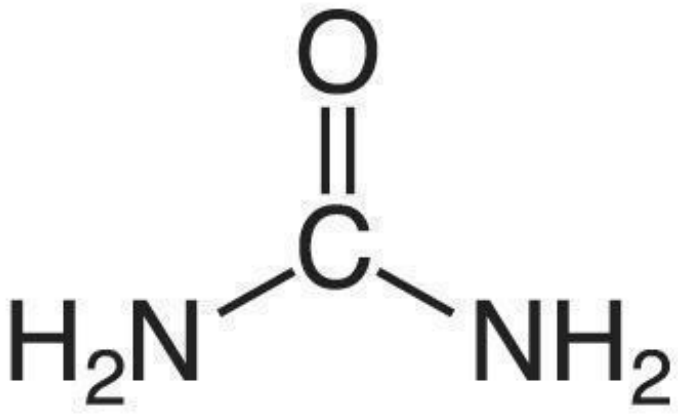
**DERMASORB XM COMPLETE KIT**

## DESCRIPTION

DERMASORB™XM (Urea 39%) Cream is a keratolytic emollient, which is a gentle, yet effective, tissue softener for skin. Each gram contains 390 mg Urea as the active ingredient and the following inactive ingredients: Dimethyl Isosorbide, Emulsifying Wax NF, Glycerin, Isopropyl Myristate, Purified Water, Sorbitol, Tridecyl Stearate and Neopentyl Glycol Dicaprylate/Dicaprate and Tridecyl Trimellitate.

Urea is diamide of carbonic acid with the following structure:




## CLINICAL PHARMACOLOGY

Urea cream gently dissolves the intracellular matrix which results in loosening of the horny layer of the skin and shedding of scaly skin at regular intervals, thereby softening hyperkeratotic areas of the skin.

## PHARMACOKINETICS

The exact mechanism of action of topically applied urea is not known.

## INDICATION AND USAGE

DERMASORB™XM (Urea 39%) Cream 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

Known hypersensitivity to any of the listed ingredients.

## WARNINGS

For external use only. Avoid contact with eyes, lips or mucous membranes.

## PRECAUTIONS

Urea cream should be used as directed by a physician and should not be used to treat conditions other than those for which it was prescribed. If redness or irritation occurs, discontinue use.

### Pregnancy: Category C

Animal reproduction studies have not been conducted with urea cream. It is also not known whether urea cream can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Urea cream should be given to a pregnant woman only if clearly needed.

### Nursing Mothers

It is not known whether urea cream is excreted in human milk, therefore caution should be exercised when administering to a nursing mother.

## ADVERSE REACTIONS

Transient stinging, burning, itching or irritation is possible and normally resolves upon discontinuing the medication.

## DOSAGE AND ADMINISTRATION

Apply to affected skin twice per day, or as directed by your physician. Rub in until completely absorbed.

KEEP THIS AND ALL OTHER MEDICATIONS OUT OF REACH OF CHILDREN

## HOW SUPPLIED

DERMASORB™XM (Urea 39%) Cream is supplied in:

227g NDC 0316-0204-01

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

Protect from freezing.

Manufactured and distributed by: Crown Laboratories, Inc. Johnson City, TN 37604

Rx Only

P9471.00

### Dermasorb XM Complete Kit

p947400


# DERMASORB XM COMPLETE KIT

urea cream with moisturizing cream kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0316-1035 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0316-1035-01 | 1 in 1 KIT | | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BOTTLE, PLASTIC | 227 g |
| **Part 2** | 1 TUBE | 227 g |

## Part 1 of 2

## DERMASORB XM

39% urea cream cream

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:0316-0204 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **UREA** (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W) | UREA | 390 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **DIMETHYL ISOSORBIDE** (UNII: SA6A6V432S) | |
| **POLAWAX POLYSORBATE** (UNII: Q504PL8E0V) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **ISOPROPYL MYRISTATE** (UNII: 0RE8K4LNJS) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **TRIDECYL STEARATE** (UNII: A8OE252M6L) | |
| **NEOPENTYL GLYCOL DICAPRYLATE/DICAPRATE** (UNII: VLW429K27K) | |
| **TRIDECYL TRIMELLITATE** (UNII: FY36J270ES) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:0316-0204-01 | 1 in 1 KIT | | |
| **1** | | 227 g in 1 BOTTLE, PLASTIC | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 11/14/2013 | |

## Part 2 of 2

## DERMASORB EXTREME MOISTURIZER

lotions, oils, powders, and creams

### Product Information

| Other Ingredients | | |
|---|---|---|
| **Ingredient Kind** | **Ingredient Name** | **Quantity** |
| INGR | **WATER** (UNII: 059QF0KO0R) | |
| INGR | **PETROLATUM** (UNII: 4T6H12BN9U) | |
| INGR | **GLYCERIN** (UNII: PDC6A3C0OX) | |
| INGR | **LIGHT MINERAL OIL** (UNII: N6K5787QVP) | |
| INGR | **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| INGR | **STEARYL ALCOHOL** (UNII: 2KR89I4H1Y) | |
| INGR | **POLYOXYL 20 CETOSTEARYL ETHER** (UNII: YRC528SWUY) | |
| INGR | **SODIUM P-CHLORO-M-CRESOL** (UNII: 343KVA8Y38) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 1 in 1 KIT | | |
| **1** | | 227 g in 1 TUBE | | |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| Cosmetic | | 11/14/2013 | |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 11/14/2013 | |

### Labeler - Crown Laboratories (079035945)

### Registrant - Crown Laboratories (079035945)

### Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Crown Laboratories | | 079035945 | manufacture(0316-1035) |