EVARA- urea 40.5 cream cream
Oncora Pharma, 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.

Evara 40.5% cream

INDICATIONS & 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 eshar. Urea is useful for the treatment of hyperkeratotic conditions such as dry, rough skin, dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis pilaris, keratosis palmaris, keratoderma, corns and calluses, as well as damaged, ingrown and devitalized nails.

CONTRAINDICATIONS

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product.

WARNINGS

Avoid contact with eyes, lips and mucous membranes.

ADVERSE REACTIONS:

Discontinue use and consult a physician if redness or irritation occurs.

DOSAGE AND ADMINISTRATION

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

Apply to diseased or damaged nail(s) twice per day, or as directed by a physician.

HOW SUPPLIED

Evara Urea 40.5% Cream 8 oz. (227 g): NDC 85477-308-08

STORAGE

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from freezing and excessive heat. Keep container tightly closed.

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

Evara

pdp

Distributed by

Oncora Pharma

Dallas, TX 75228

EVARA urea 40.5 cream cream			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:85477-308
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
UREA (UNII: 8W8T17847W) (UREA - UNII:8W8T17847W)	UREA	405 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
WATER (UNII: 059QF0KO0R)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL STEARATE (UNII: 230OU9XXE4)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
GLYCERIN (UNII: PDC6A3C0OX)	
PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL (UNII: 66YXD4DKO9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-308-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/29/2026	

Labeler - Oncora Pharma, LLC (119482542)

Revised: 5/2026 Oncora Pharma, LLC