

LOUTREX- dressing, wound, drug cream
Acella Pharmaceuticals, LLC

Loutrex

Topical Cream

For Topical Dermatological Use Only

Rx only

For External Use Only

Product Description: Loutrex Topical Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.

Indications for Use: Under the supervision of a healthcare professional, Loutrex Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Loutrex Topical Cream helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Contraindications: The use of Loutrex Topical Cream is contraindicated in any patient with a known hypersensitivity to any of the ingredients.

Directions for Use: Apply Loutrex Topical Cream to the affected skin areas 2 or 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover Loutrex Topical Cream with a dressing of choice.

Ingredients: Loutrex Topical Cream is comprised of Allantoin, Ascorbyl Tetraisopalmitate, Bisabolol, Butylene Glycol, Butyrospermum Parkii, Cera Alba, Citric Acid, Citrus Grandis (Grapefruit) Fruit Extract, Citrus Limon (Lemon) Fruit Extract, Disodium EDTA, Ethylhexyl Palmitate, Glycerylrrhethinic Acid, Hydrogenated Castor Oil, Isohexadecane, Magnesium Stearate, Magnesium Sulfate, PEG-30 Dipolyhydroxystearate, Pentylene Glycol, Piroctone Olamine, Polyglyceryl-6 Polyricinoleate, Propyl Gallate, Propylene Glycol, Purified Water, Tocopheryl Acetate and Vitis Vinifera.

Precautions: Loutrex Topical Cream does not contain milk, wheat, peanut or animal derivatives. Loutrex Topical Cream does contain shea butter (Butyrospermum parkii), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

How Supplied: 30 g tube, 42192-610-30. The listed product number is not a National Drug Code, but has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

To Open: Peel foil seal away and discard.

Important: The opening of this product is covered by an aluminum seal. Do not use if seal has been broken or is not visible.

Store at controlled room temperature 68° to 77°F (20° to 25°C), excursions permitted between 59° and 86°F (15° and 30°C). Do **NOT** refrigerate.

Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Manufactured for:

Acella
PHARMACEUTICALS, LLC
Alpharetta, GA 30022
1-800-541-4802

Rev. 0413

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30g topical cream carton

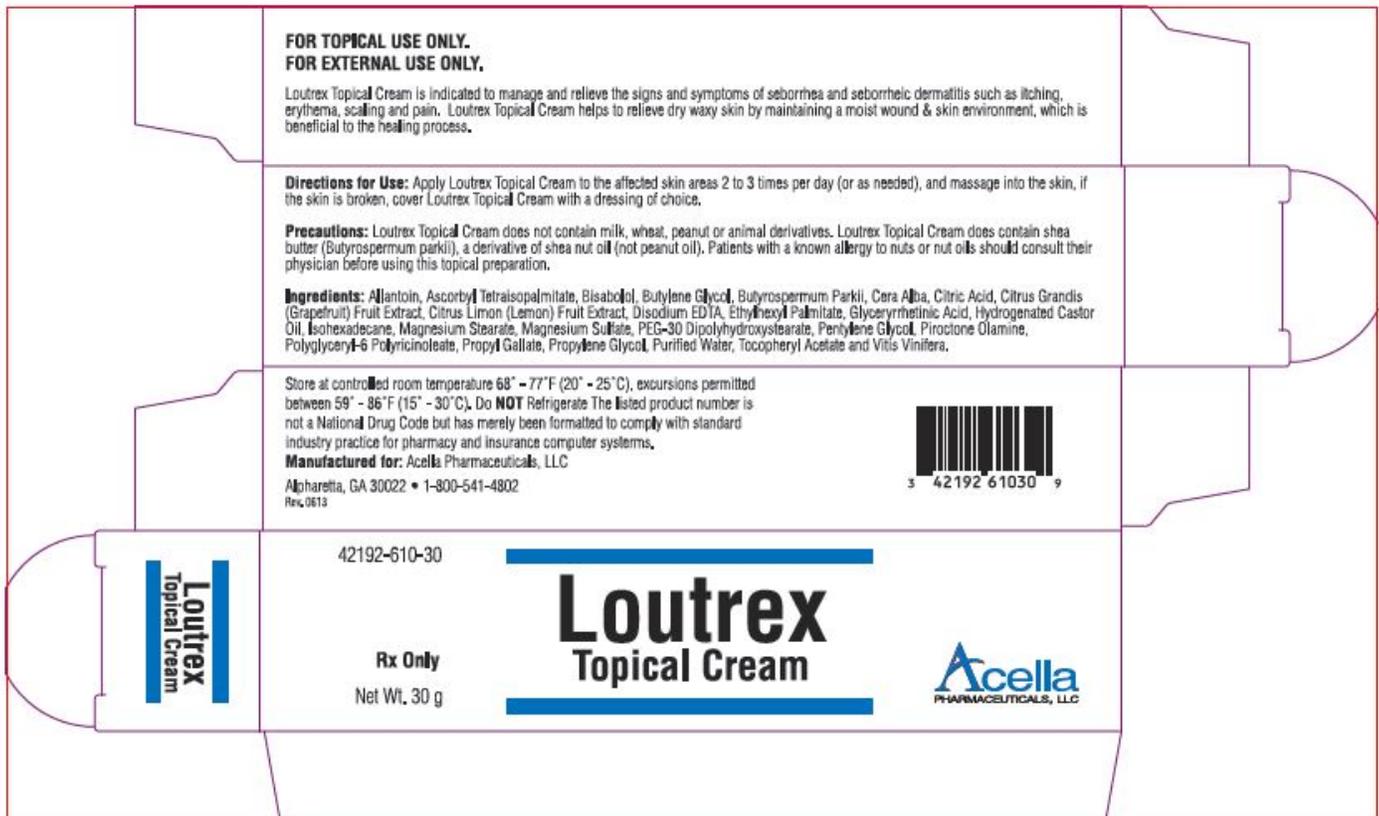
42192-610-30

**Loutrex
Topical Cream**

Rx Only

**Acella
PHARMACEUTICALS, LLC**

Net Wt. 30 g



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 Gram Tube Label

42192-610-30

**Loutrex
Topical Cream**

Rx Only

**Acella
PHARMACEUTICALS, LLC**

Net Wt. 30 g

3 X 6 MM 7 MM

seal area

FOR TOPICAL USE ONLY.
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Directions: Apply Loutrex Topical Cream to the affected skin areas 2 to 3 times per day (or as needed), and massage into the skin, if the skin is broken, cover Loutrex Topical Cream with a dressing of choice.
To Open: Peel foil seal away and discard. Do not use if seal is not visible.
Important: The opening of this product is covered by an aluminum seal.
Caution: Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.
 See complete package for complete prescribing and ingredient information.
 Store at controlled room temperature 68° - 77°F (20° - 25°C), excursions permitted between 59° - 86°F (15° - 30°C). Do **NOT** Refrigerate.
Manufactured for: Acella Pharmaceuticals, LLC, Alpharetta, GA 30009
 1-800-541-4802 Rev. 0212



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42192-610-30

Loutrex Topical Cream

Rx Only
Net Wt. 30 g



LOUTREX

dressing, wound, drug cream

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:42192-610
Route of Administration	TOPICAL		

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ALLANTOIN (UNII: 344S277G0Z)	
INGR	ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	WHITE WAX (UNII: 7G1J5DA97F)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	PUMMELO (UNII: ET1TN5W71X)	
INGR	LEMON (UNII: 24RS0A988O)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	ENOXOLONE (UNII: P540XA09DR)	
INGR	HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
INGR	ISOHEXADECANE (UNII: 918X10UF1E)	

INGR	MAGNESIUM STEARATE (UNII: 70097M6I30)	
INGR	MAGNESIUM SULFATE (UNII: DE08037SAB)	
INGR	PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	PIROCTONE OLAMINE (UNII: A4V5C6R9FB)	
INGR	POLYGLYCEROL POLYRICINOLEIC ACID (UNII: 3C96Y1D5T4)	
INGR	PROPYL GALLATE (UNII: 8D4SNN7V92)	
INGR	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
INGR	WINE GRAPE (UNII: 3GOV20705G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:42192-610-30	1 in 1 CARTON		
1		30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K120730	11/25/2013	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Revised: 3/2014

Acella Pharmaceuticals, LLC