LIDOCAINE HYDROCHLORIDE- dressing, wound and burn, hydrogel w/drug and/or biologic gel
Gensco Laboratories, LLC

LDO Plus (Lidocaine HCl USP) 4%

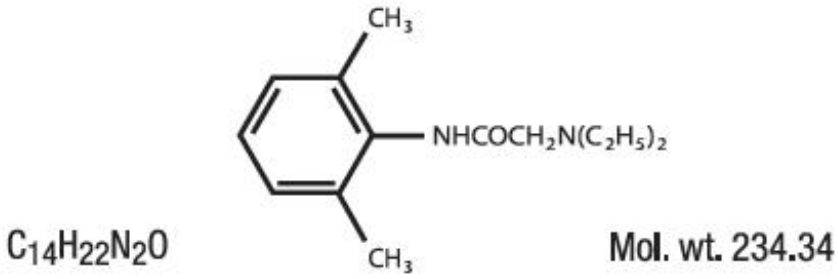
Rx only

DO NOT USE IN THE EYES.

DESCRIPTION

A soothing hydrogel wound dressing that promotes a moist wound environment that is ideal for the healing process

LDO Plus contains Lidocaine HCl USP 4%, which is chemically designated as acetamide, 2-(diethylamino)-*N*-(2,6-dimethylphenyl)-, and has the following structural formula:



INDICATIONS AND USAGE

- Stage I - IV pressure ulcers
- Venous stasis ulcers
- Ulcerations caused by mixed vascular etiologies
- Diabetic skin ulcers
- First and second degree burns
- Post-surgical incisions, cuts and abrasions.

CONTRAINDICATIONS

LDO Plus contains Lidocaine Hydrochloride USP and is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of LDO Plus.

Do not use LDO Plus on traumatized mucosa or in the presence of secondary bacterial infection of the area of proposed application.

WARNINGS

Do not use this product if you are allergic to any ingredients. If condition worsens or does not improve within 7 days, consult a physician. Do not use on children under 2 years of age without consulting a physician.
Avoid contact with eyes. Do not use in large quantities.

For external use only. Not for ophthalmic use.
Keep out of reach of children.

PRECAUTIONS

If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate therapy. LDO Plus Hydrogel should be used with caution in ill, elderly, debilitated patients and children who may be more sensitive to the systemic effects of Lidocaine Hydrochloride USP. In case of accidental ingestion get medical help or contact poison control center right away.

CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY

Studies of lidocaine in animals to evaluate the carcinogenic potential of the effect on fertility have not been conducted.

USE IN PREGNANCY

Teratogenic Effects:

Teratogenic Effects. Pregnancy Category B. Reproduction studies have been performed in rats at doses up to 6.6 times the human dose and have revealed no evidence of harm to the fetus caused by Lidocaine Hydrochloride USP. There are, however, no adequate and well-controlled studies in pregnant women. Animal reproduction studies are not always predictive of human response. General consideration should be given to this fact before administering Lidocaine Hydrochloride USP to women of childbearing potential, especially during early pregnancy when maximum organogenesis takes place.

NURSING MOTHERS:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lidocaine Hydrochloride USP. is administered to a nursing woman.

PEDIATRIC USE:

Dosage in children should be reduced, commensurate with age, body weight and physical condition. Caution must be taken to avoid over dosage when applying LDO Plus to large areas of injured or abraded skin, since the systemic absorption of Lidocaine Hydrochloride USP may be increased under such conditions.

ADVERSE REACTIONS:

Adverse experiences following the administration of Lidocaine Hydrochloride USP are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient.
Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

Central Nervous System:

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest. Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular system

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic

Allergic reactions are characterized by cutaneous lesions, urticaria, edema or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

DOSAGE AND ADMINISTRATION:

Administration

Cleanse the wound and blow it dry. Apply a thin layer of LDO Plus to the wound surface and the skin immediately surrounding the wound 3-4 times daily.

STORAGE AND HANDLING

Store at 25ºC (77ºF); excursions permitted to 15º-30ºC (59º-86º F). See USP Controlled Room Temperature. Protect from freezing.

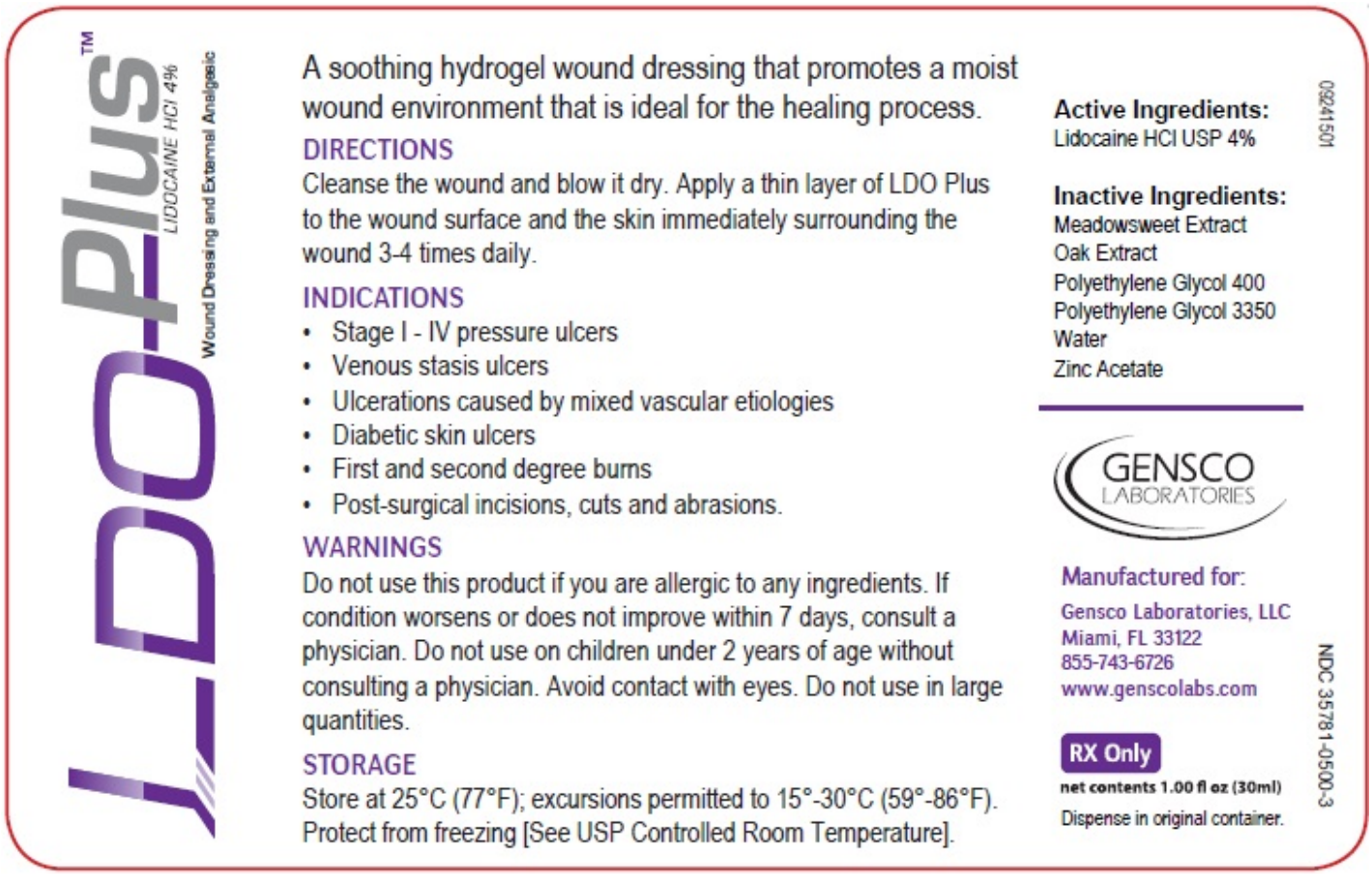
HOW SUPPLIED

LDO Plus (Lidocaine HCl USP 4%)

1/2 oz (15g) 15mL Airless Pump - NDC 35781-0500-1
1.00 oz (30g) 30mL Airless Pump - NDC 35781-0500-3
3.00 oz (90g) 90mL Airless Pump - NDC 35781-0500-9

Gensco Labratories, LLC
8550 NW 33rd St Suite 200
Doral, FL 33122

LIDOCAINE HCL (LIDOCAINE HCL) HYDROGEL



LIDOCAINE HYDROCHLORIDE

dressing, wound and burn, hydrogel w/drug and/or biologic gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NHRIC:35781-0500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
FILIPENDULA ULMARIA FLOWER (UNII: 06L18L32G6)	
QUERCUS ALBA WOOD (UNII: XR6BC2ZUAM)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
WATER (UNII: 059QF0KO0R)	
ZINC ACETATE (UNII: FM5526K07A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:35781-0500-1	1 in 1 CARTON		
1		15 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NHRIC:35781-0500-3	1 in 1 CARTON		
2		30 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
3	NHRIC:35781-0500-9	1 in 1 CARTON		
3		90 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Premarket Notification	K092086	06/30/2009	

Labeler - Gensco Laboratories, LLC (831042325)

Registrant - Gensco Laboratories, LLC (831042325)

Establishment

Name	Address	ID/FEI	Business Operations
Gensco Laboratories, LLC		831042325	manufacture(35781-0500)

Revised: 10/2015 Gensco Laboratories, LLC