

ASTERO- dressing, wound and burn, hydrogel w/drug and/or biologic gel
Lake Erie Medical DBA Quality Care Products LLC

ASTERO (Lidocaine HCl USP) 4%

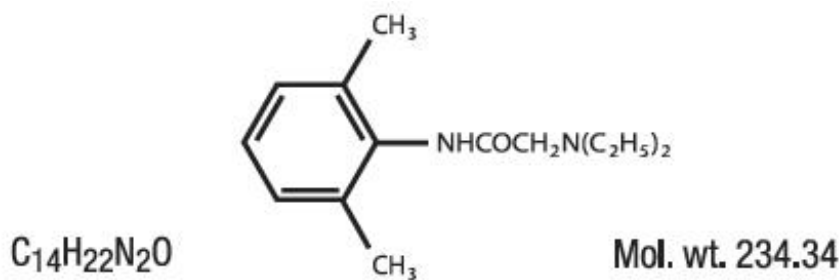
Rx only

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

ASTERO 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

Astero™ is a medicated Hydrogel wound dressing in a Metered Dose (M-DOSE™) bottle containing lidocaine 4%, an amide type local anesthetic, indicated for:
Painful wounds such as post-surgical incisions, cuts and abrasions.

CONTRAINDICATIONS

Traumatized mucosa, secondary bacterial infection of the area of proposed application and known hypersensitivity to any of the components.

Lidocaine Hydrochloride USP is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type.

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. Avoid Contact with Eyes.

Keep out of reach of children.

PRECAUTIONS

If irritation or sensitivity occurs or infection appears, discontinue use and institute appropriate

therapy. Astero 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.

CARCINOGENESIS, MUTAGENESIS, AND IMPAIRMENT OF FERTILITY

Studies of Lidocaine Hydrochloride USP in animals to evaluate the carcinogenic and mutagenic potential or the effect on fertility have not been conducted.

USE IN PREGNANCY

Teratogenic Effects:

Teratogenic Effects of Lidocaine Hydrochloride USP. 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:

Lidocaine Hydrochloride USP is not contraindicated in labor and delivery. Should Astero be used concomitantly with other products containing Lidocaine Hydrochloride USP, the total dose contributed by all formulations must be kept in mind.

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 Astero to large areas of injured or abraded skin, since the systemic absorption of Lidocaine Hydrochloride USP may be increased under such conditions. Do not use on children under 2 unless directed by a physician.

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 of Lidocaine toxicity 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 Hydrochloride USP 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 of Lidocaine toxicity 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 Hydrochloride USP 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 ASTERO to the wound surface and the skin immediately surrounding the wound 3-4 times daily.

STORAGE AND HANDLING

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

HOW SUPPLIED

ASTERO (Lidocaine HCl USP 4%)

1.0 oz (28.5g) 30mL Airless Pump - NDC 35781-2500-3

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

Packaged and Distributed by

Quality Care Products, LLC

1-800-337-8603



Holland, OH 43528

ASTERO
(LIDOCAINE HCl 4%)

Warning: Keep out of children's reach.
Store at 77 degrees F.

Consult with a physician. See manufacturer's insert.



GTIN: 00355700421304

NDC: 55700-0421-30

Serial:

1.0 FL OZ (30 ml)

Lot:

HYDROGEL + TOPICAL ANESTHETIC

EXP: //

Rx only

Active Ingredients: Lidocaine HCl USP 4%

Mfr for: Gensco Laboratories, LLC, Miami, FL 33122

ASTERO
1.0 FL OZ (30 ml)
Lot: //
EXP: //
NDC: 55700-0421-30

ASTERO
1.0 FL OZ (30 ml)
Lot: //
EXP: //
NDC: 55700-0421-30

SOURCE CODE: 3578125003

ASTERO

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

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:55700-421(NDC:35781- 2500)	
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:55700- 421-30	1 in 1 CARTON		
1		30 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		
2	NHRIC:55700- 421-90	1 in 1 CARTON		
2		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	07/05/2016		

Labeler - Lake Erie Medical DBA Quality Care Products LLC (831276758)