Pelashield™ PainGuard™ with Lidocaine

SAM™ Antimicrobial Technology

INSTRUCTIONS

Imbed BIOSCIENCES

DESCRIPTION: Pelashield™ PainGuard™ is a sterile, single use absorbent polymeric matrix composed primarily of synthetic polyvinyl alcohol with 2.5 mg/in^2 of lidocaine hydrochloride USP, with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver with a maximum of 0.1 mg/in^2 of silver.

MECHANISM OF ACTION: Pelashield™ PainGuard™ absorbs wound fluid and forms a soft matrix that conforms to the wound surface and maintains a moist environment. The matrix contains silver only to prevent or minimize microbial growth within the matrix. The dressing releases Lidocaine Hydrochloride USP for effecting local anesthetic action in painful skin wounds.

INTENDED USE: Pelashield™ PainGuard™ is intended for use as a primary dressing in the local management of wounds. Under the supervision of a healthcare professional, Pelashield™ PainGuard™ may be used for the management of partial and full thickness wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first-degree burns, partial thickness burns, abrasions and lacerations.

INDICATIONS FOR USE:
Under the supervision of a healthcare professional, Pelashield™ PainGuard™ may be used for the management of partial and full thickness wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first degree burns, partial thickness burns, abrasions and lacerations.

DIRECTIONS FOR USE:
- Clean the wound area using sterile saline solution.
- If the wound is dry, moisten it with sterile saline and remove excess saline with sterile gauze.
- Avoid contact of the dressing with wet surfaces until placed on a moist wound bed.
- Cut the dressing to size slightly larger than the wound. Multiple sheets of the dressing can be used cover the entire wound area.
- Apply the dressing directly to wound bed. When placed on a moist wound bed, the matrix conforms to the wound bed. Clinicians, at their discretion, may use appropriate mechanical fixation, covering, or closure techniques.
- Pelashield™ PainGuard™ should be used with a secondary cover dressing. Cover with a moisture retentive dressing such as, a film dressing, foam dressing, gauze or other appropriate dressing. See individual cover dressing package inserts for complete instructions for use. All dressing site areas should be inspected daily.
- Pelashield™ PainGuard™ can be applied from the onset and for the duration of the wound, every 3 days or at the discretion of the health care practitioner depending on the wound and the healing progression, or when clinically indicated (e.g. leakage, excessive bleeding, increased pain). A single dose of lidocaine HCl should not exceed 300 mg (4.5 mg/kg of body weight).
- The wound should be re-evaluated on a weekly basis.
- To reapply, carefully remove the secondary cover dressing(s). Gently irrigate wound with sterile saline to remove necrotic tissue. It is not necessary to remove any residual matrix observed during secondary cover dressing changes.
- Change the secondary cover dressing as needed or when Pelashield™ PainGuard™ is re-applied.
- Duration of treatment depends on wound type and healing conditions.

WARNINGS AND PRECAUTIONS:
- Avoid Contact with Eyes.
- Frequent or prolonged use of this product may result in permanent discoloration of skin.
- Avoid use with iodophor containing products that may reduce the effectiveness of silver in the dressing.
- If irritation or sensitivity occurs, discontinue use and institute appropriate therapy.
- Pelashield™ PainGuard™ should be used with caution in patients who may be more sensitive to the systemic effects of Lidocaine Hydrochloride USP.
- The wound should be inspected during dressing changes. Consult a healthcare professional if you see (a) signs of infection (increased pain, increased redness, wound drainage), (b) bleeding, (c) a change in wound color and/or odor, (d) irritation (increased redness and/or inflammation), (e) maceration (skin whitening), (f) hypergranulation (excessive tissue formation), (g) sensitivity (allergic reaction), (h) no signs of healing.
- This product contains < 0.5 mg/in^2 polyethylene glycol (400 Da).
- Appropriate supportive measures should be taken as indicated. For example, use of granulation compression in the management of pressure ulcers, systemic antibiotics and frequent monitoring of treatment of wound infection, control of blood glucose for diabetic ulcers, etc.

SAFETY & EFFECTIVENESS: Preclinical testing has been performed on Pelashield™ PainGuard™ and its biocompatibility has been demonstrated through appropriate in vitro and in vivo tests, including cytotoxicity, sensitization, acute intracutaneous reactivity, acute systemic toxicity, subacute/subchronic systemic toxicity, tissue implantation, material mediated pyrogenicity, and porcine wound healing studies. Sustained antimicrobial activity within the dressing has been demonstrated for up to 3 days by relevant standard in vitro microbiological assays in simulated wound fluid. Pelashield™ PainGuard™ was shown to be effective in killing within the dressing more than 4 log10 CFUs of microbes most frequently isolated in clinics, including, S. aureus (ATCC 6538), MRSA (ATCC 33591), E. coli (ATCC 8739), P. aeruginosa (ATCC 9027), K. pneumoniae (ATCC 4352), E. faecalis (ATCC 51575), C. tropicalis (ATCC 750) and C. albicans (ATCC 10231). The product has been determined to be non-pyrogenic.

CONTRAINDICATIONS: Do not use on individuals who are sensitive to silver, lidocaine, or any local anesthetics of the amide type. Do not use on individuals who have had an allergic reaction to the dressing or one of its components.

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:

1. 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.
2. 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.
3. 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.

DRUG INTERACTIONS:

1. Serious interactions:
   a. Antiarrhythmic Drugs: Lidocaine Hydrochloride USP should be used with caution in patients receiving Class I antiarrhythmic drugs (such as tocainide and mexiletine) since the toxic effects are additive and potentially synergistic.
   b. Bupivacaine liposome: Lidocaine Hydrochloride USP increases toxicity of Bupivacaine by increasing the free (unencapsulated) bupivacaine.
   c. Dofetilide: Lidocaine Hydrochloride USP increases effects of dofetilide through pharmacodynamic synergism.
   d. Lomitapide: Lidocaine Hydrochloride USP increases levels of lomitapide by affecting hepatic/intestinal enzymes CYP3A4 metabolism.
2. General interactions: Drugs metabolized via CYP3A4 enzyme: (ex. Antipsychotics, SSRIs, TCAs, many chemotherapeutics, calcium channel bockers, benzodiazopines) Lidocaine Hydrochloride USP may increase serum levels of many drugs metabolized by hepatic / intestinal CYP3A4 enzymes. Drugs that affect hepatic CYP1A2 enzyme: (ex. Quinoline antibiotics, cimetidine, barbiturates, benzodiazepines, erythromycin) May increase serum Lidocaine Hydrochloride USP levels by decreasing Lidocaine Hydrochloride USP metabolism by CYP1A2 enzyme.

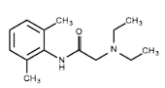
USE IN SPECIFIC POPULATIONS:

1. Use in Pregnancy: 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.
2. Labor and Delivery: Lidocaine Hydrochloride USP is not contraindicated in labor and delivery. Should Pelashield™ PainGuard™ be used concomitantly with other products containing Lidocaine Hydrochloride USP, the total dose contributed by all formulations must be kept in mind.
3. 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.
4. Pediatric use: Dosage in children should be reduced, commensurate with age, body weight and physical condition. Do not use on children under 2 unless directed by a physician.
5. Geriatric use: No overall clinical differences in safety or effectiveness have been observed between the healthy elderly and other adult patients.

OVER DOSAGE: Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. (see WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS).

Management of local anesthetic emergencies: The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anesthetic administration. At the first sign of change, oxygen should be administered. The first step in the management of convulsions consists of immediate attention to the maintenance of a patient airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine). If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures should be instituted. Dialysis is of negligible value in the treatment of acute over dosage with Lidocaine Hydrochloride USP. The oral LD50 of Lidocaine Hydrochloride USP in non-fasted female rats is 459 (346-773) mg/kg (as the salt) and 214 (159-324) mg/kg (as the salt) in fasted female rats.

INGREDIENTS:
Active ingredients: Each film of Pelashield™ PainGuard™ contains Lidocaine Hydrochloride USP, which is chemically designated as acetamide, 2- (diethylamino)-N-(2,6-dimethylphenyl), and has the following structure:



CLINICAL PHARMACOLOGY:

1. Onset of anesthesia: Pelashield™ PainGuard™ effects local, topical anesthesia. The onset of action is 3-5 minutes.
2. Hemodynamics: Excessive blood levels may cause changes in cardiac output, total peripheral resistance, and mean arterial pressure. These changes may be attributable to a direct depressant effect of the local anesthetic agent on various components of the cardiovascular system.
3. Pharmacokinetics and metabolism: Lidocaine Hydrochloride USP may be absorbed following topical administration to mucous membranes or open wounds, its rate and extent of absorption depending upon the specific site of application, duration of exposure, concentration, and total dosage. In general, the rate of absorption of local anesthetic agents following topical application occurs most rapidly after intratracheal administration. Lidocaine Hydrochloride USP is also well-absorbed from the gastrointestinal tract, but little intact drug appears in the circulation because of biotransformation in the liver. Lidocaine Hydrochloride USP is metabolized rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of Lidocaine Hydrochloride USP. Approximately 90% of Lidocaine Hydrochloride USP administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2,6-dimethylaniline. The plasma binding of Lidocaine Hydrochloride USP is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 µg of free base per mL, 60 to 80 percent of Lidocaine Hydrochloride USP is protein bound. Binding is also dependent on the plasma concentration of the alpha-l-acid glycoprotein. Lidocaine Hydrochloride USP crosses the blood-brain and placental barriers, presumably by passive diffusion. Studies of Lidocaine Hydrochloride USP metabolism following intravenous bolus injections have shown that the elimination half-life of this agent is typically 1.5 to 2.0 hours. Because of the rapid rate at which Lidocaine Hydrochloride USP is metabolized, any condition that affects liver function may alter Lidocaine Hydrochloride USP kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect Lidocaine Hydrochloride USP kinetics but may increase the accumulation of metabolites. Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of Lidocaine Hydrochloride USP required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6.0 µg free base per mL. In the rhesus monkey arterial blood levels of 18-21 µg/mL have been shown to be threshold for convulsive activity

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

STORAGE CONDITIONS: Store at room temperature (15°C/59°F – 30°C/86°F). Keep dry. If further information is needed, please contact Imbed Biosciences Inc.

HOW SUPPLIED: Pelashield™ PainGuard™ is individually packaged in a foil pouch. Sterilization by E-beam radiation. Sterile unless pouch is damaged or opened. Single use only.

EXPLANATION OF SYMBOLS

LOT	Batch Code		Do not use if package is damaged
REF	Part number		Use by date
	Caution, consult documentation	15°C 30°C	Store between 15°C/59°F and 30°C/86°F
STERILE R	Sterilized using e-beam radiation	LATEX	Latex-free
	Re-use is not allowed		Manufacturer
MR	MR Unsafe	Rx Only	Prescription Device

MANUFACTURED BY
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