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EMLA

(Prilocaine, Lidocaine) - APP Pharmaceuticals

THERAPEUTIC CLASS
Acetamide local anesthetic

DEA CLASS
RX

INDICATIONS
Topical anesthetic for use on normal intact skin. Topical anesthetic for genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.

ADULT DOSAGE
Adults: Apply thick layer of cream to intact skin and cover with occlusive dressing. Minor Dermal Procedure: Apply 2.5g over 20-25cm^2 of skin surface for at least 1 hr. Major Dermal Procedure: Apply 2g/10cm^2 of skin for 2 hrs. Adult Male Genital Skin: Apply 1g/10cm^2 of skin surface for 15 min. Female External Genitalia: Apply 5-10g for 5-10 min.

PEDIATRIC DOSAGE
Pediatrics: 7-12 Yrs and >20kg: Max: 20g/200cm^2 for up to 4 hrs. 1-6 Yrs and >10kg: Max:10g/100cm^2 for up to 4 hrs. 3-12 Months and >5kg: Max: 2g/20cm^2 for up to 4 hrs. 0-3 Months or <5kg: Max: 1g/10cm^2 for up to 1 hr. If >3 months and does not meet minimum weight requirement, max dose restricted to corresponding weight.

HOW SUPPLIED
Cre: (Lidocaine-Prilocaine) 2.5%-2.5%

WARNINGS/PRECAUTIONS
Application to larger areas or for longer than recommended times, may result in serious adverse effects. Should not be used where penetration or migration beyond the tympanic membrane into the middle ear is possible. Avoid with congenital or idiopathic methemoglobinemia and in infants <12 months of age receiving treatment with methemoglobin-inducing agents. Very young or patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more susceptible to methemoglobinemia. Reports of methemoglobinemia in infants and children following excessive applications. Monitor neonates and infants up to 3 months of age for Met-Hb levels before, during, and after application. Repeated doses may increase blood levels; caution in patients who may be more susceptible to systemic effects (eg, acutely ill, debilitated, elderly). Avoid eye contact and application to open wounds. Has been shown to inhibit viral and bacterial growth. Caution with severe hepatic disease and in patients with drug sensitivities.

ADVERSE REACTIONS
Erythema, edema, abnormal sensations, paleness (pallor or blanching), altered temperature sensations, burning sensation, itching, rash.

DRUG INTERACTIONS
Additive and potentially synergistic toxic effects with Class I antiarrhythmic drugs (eg, tocainide, mexiletine). May have additive cardiac effects with Class III antiarrhythmic drugs (eg, amiodarone, bretylium, sotalol, dofetilide). Avoid drugs associated with drug-induced methemoglobinemia (eg, sulfonamides, acetaminophen, acetanilid, aniline dyes, benzocaine, chloroquine, dapsone, naphthalene, nitrates/nitrites, nitrofurantoin, nitroglycerin, nitroprusside, phenobarbital, phenytoin, primaquine, pamaquine, para-aminosalicylic acid, phenacetin, quinine). Caution with other products containing lidocaine/prilocaine; consider the amount absorbed from all formulations.

PREGNANCY
Category B, caution in nursing.

MECHANISM OF ACTION
Amide-type local anesthetics; stabilizes neuronal membranes by inhibiting ionic fluxes required for initiation and conduction impulses, thereby affecting local anesthetic action.

PHARMACOKINETICS
Absorption: Lidocaine: (3 hrs 400cm^2) C_{max}=0.12mcg/mL, T_{max}=4 hrs; (24 hrs 400cm^2) C_{max}=0.28mcg/mL, T_{max}=10 hrs. Prilocaine: (3 hrs 400cm^2) C_{max}=0.07mcg/mL, T_{max}=4 hrs; (24 hrs 400cm^2) C_{max}=0.14mcg/mL, T_{max}=10 hrs. **Distribution:** (IV) V_d=1.5L/kg (lidocaine), 2.6L/kg (prilocaine); (Cre) plasma protein binding 70% (lidocaine), 55% (prilocaine). Crosses placental and blood-brain barrier; found in breast milk. **Metabolism:** Lidocaine: Liver (rapid); monoethylglycinexylidide and glycinexylidide (active metabolites). Prilocaine: Liver and kidneys by amidases; ortho-toluidine and N-n-propylalanine (metabolites). **Elimination:** (IV) Lidocaine: Urine (>98%); $T_{1/2}$=110 min. Prilocaine: $T_{1/2}$=70 min.

ASSESSMENT
Assess for congenital or idiopathic methemoglobinemia, G6PD deficiency, hepatic disease, open wounds, presence of acute illness, presence of debilitation, history of drug sensitivities, pregnancy/nursing status, and for possible drug interactions. In neonates and infants ≤3 months of age, obtain Met-Hb levels prior to application.

MONITORING

Monitor for signs/symptoms of methemoglobinemia, ototoxicity, local skin reactions and for allergic/anaphylactoid reactions. Monitor Met-Hb levels in neonates and infants ≤3 months of age during and after application.

PATIENT COUNSELING

Inform about potential risks/benefits of drug. Advise to avoid inadvertent trauma to treated area. Instruct not to apply near eyes or on open wounds. Apply as directed by physician. Advise to notify physician if pregnant/nursing or planning to become pregnant. Instruct to remove cream and consult physician if child becomes very dizzy, excessively sleepy, or develops duskiness on the face or lips after application.

ADMINISTRATION/STORAGE

Administration: Topical route. Not for ophthalmic use. **Storage:** 20-25°C (68-77°F). Keep tightly closed.