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מרץ 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון: עדכון העלון לרופא של התכשיר אוקטוקאין 100 – OCTOCAINE 100
Lidocaine Hydrochloride (as Monohydrate) 2% and Epinephrine (as Bitartrate) 1:100,000 Solution for injection

חברת דנטאוריינט פוס בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר אוקטוקאין 100 – Octocaine 100 בהודעה זו מצויינים העדכונים המהותיים בלבד בעלון לרופא. בעלון ישנם שינויים נוספים.

התוויה הרשומה לתכשיר בישראל (נותרה ללא שינוי):
For the production of local anaesthesia for dental procedures by nerve block or infiltration technique.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

2) Qualitative and quantitative composition:
1 ml of solution for injection contains 20 mg of Lidocaine Hydrochloride (as Monohydrate) and 10 micrograms (1:100,000) of Epinephrine (as Bitartrate). Epinephrine Bitartrate is also called Adrenaline Tartrate. Both names are synonyms.
One cartridge of 1.8 ml of solution for injection contains 36 mg of Lidocaine Hydrochloride (as Monohydrate) and 18 micrograms of Epinephrine (as Bitartrate). Excipient(s) with known effect: This medicinal product contains 1.20 mg/ml Potassium Metabisulfite [equivalent to 0.422 mg/ml Potassium (0.0108 mmol/ml)].
For a full list of excipients, see section 6.1.
4.4) Special warnings and precautions for use:
WARNINGS:
DENTAL PRACTITIONERS WHO EMPLOY LOCAL ANESTHETIC AGENTS SHOULD BE WELL VERSED IN DIAGNOSIS AND MANAGEMENT OF EMERGENCIES WHICH MAY ARISE FROM THEIR USE. RESUSCITATIVE EQUIPMENT, OXYGEN AND OTHER RESUSCITATIVE DRUGS SHOULD BE AVAILABLE FOR IMMEDIATE USE.
To minimize the likelihood of intravascular injection, aspiration should be performed before the local anesthetic solution is injected. If blood is aspirated, the needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not assure that intravascular injection will be avoided.
Local anesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.
OCTOCAINE 100 contains potassium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.
The American Heart Association has made the following recommendations regarding the use of local anesthetics with vasoconstrictors in patients with ischemic heart disease: 'Vasoconstrictor agents should be used in local anesthesia solutions during dental practice only when it is clear that the procedure will be shortened or the analgesia rendered more profound. When a vasoconstrictor is indicated, extreme care should be taken to avoid intravascular injection. The minimum possible amount of vasoconstrictor should be used." (Kaplan, EL, editor: Cardiovascular disease in dental practice, Dallas 1986, American Heart Association.)
Methemoglobinemia: Cases of methemoglobinemia have been reported in association with local anesthetic use; Lidocaine, along with other local anesthetics, is capable of producing this condition. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.
Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and are characterized by cyanosis of the skin, nail beds and lips, and/or abnormal coloration of the blood, fatigue and weakness. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue lidocaine and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. If methemoglobinemia does not respond to administration of oxygen, a more severe clinical presentation may require treatment with methylene blue exchange transfusion, or hyperbaric oxygen.
PRECAUTIONS:
General: The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions and readiness for emergencies. Consult standard textbooks for specific techniques and precautions for various regional anesthetic procedures. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use (See sections 4.4 and 4.8).
The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose due to slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical condition.
If sedatives are employed to reduce patient apprehension, reduced doses should be used since local anesthetic agents, like sedatives, are central nervous system depressants which in combination may have an additive effect. Young children should be given minimal doses of each agent.
Lidocaine should be used with caution in patients with severe shock or heart block. Lidocaine should also be used with caution in patients with impaired cardiovascular function. Local anesthetic solutions containing a vasoconstrictor should be used with caution in areas of the body supplied by end arteries or having otherwise compromised blood supply. Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury (such as exfoliating or ulcerating lesions) or necrosis may result. Preparations containing a vasoconstrictor should be used with caution in patients during or following the administration of potent general anesthetic agents, since cardiac arrhythmias may occur under such conditions.
Cardiovascular and respiratory (adequacy of ventilation) vital signs and the patients state of consciousness should be monitored after each local anesthetic injection. Restlessness, anxiety tinnitus, dizziness, blurred vision, tremors, depression or drowsiness should alert the practitioner to the possibility of central nervous system toxicity. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position : placing the patient in the recumbent position is recommended when an adverse response is noted after injection of a local anesthetic (See section 4.8 - Cardiovascular System). Vasovagal reactions may elicit a range of clinical manifestations, from prodome signs of pre-syncope (e.g. lightheadedness, pallor, nausea, sweating, visual disturbances, weakness) to brief loss of consciousness (i.e. syncope).
Lidocaine should be used with caution in patients with hepatic disease, since amide-type local anesthetics are metabolized by the liver. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at greater risk of developing toxic plasma concentrations.
Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction, and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure and metabolic acidosis may precede temperature elevation. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspected triggering agent (s) and prompt treatment, including oxygen therapy, dantrolene (consult dantrolene sodium intravenous package insert before using) and other supportive measures.
Lidocaine should be used with caution in persons

with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine

Use in the Head and Neck Area: Small doses of local anesthetics injected into the head and neck area, including retrobulbar, dental and stellate ganglion blocks, may produce adverse reactions similar to systemic toxicity seen with unintentional intravascular injections of larger doses. Confusion, convulsions, respiratory depression and/or respiratory arrest, and cardiovascular stimulation or depression have been reported. These reactions may be due to intra-arterial injection of the local anesthetic with retrograde flow to the cerebral circulation. Patients receiving these Mocks should have their circulation and respiration monitored and be constantly observed. Resuscitative equipment and personnel for treating adverse reactions should be immediately available. Dosage recommendations should not be exceeded (See section 4.2).

Information for Patients/Patient Counseling Information: The patient should be informed of the possibility of temporary loss of sensation and muscle function following infiltration or nerve block injections.

The patient should be advised to exert caution to avoid inadvertent trauma to the lips, tongue, cheek mucosae or soft palate when these structures are anesthetized. The ingestion of food should therefore be postponed until normal function returns. The patient should be advised to consult the dentist if anesthesia persists or if a rash develops. Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

הנדון: עדכון העלון לרופא של התכשיר
איזוקאין 3% – ISOCAINE 3%
Mepivacaine Hydrochloride 3% Solution for injection

חברת דנטאוריינט פוס בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר איזוקאין 3% – Isocaine 3%.

בהודעה זו מצויינים העדכונים המהותיים בלבד בעלון לרופא. בעלון ישנם שינויים נוספים.

התוויה הרשומה לתכשיר בישראל (נותרה ללא שינוי):
Production of local anaesthesia for dental procedures by infiltration or nerve block in adults and children.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

2) Qualitative and quantitative composition:
1 ml solution for injection contains 30 mg of mepivacaine hydrochloride.
Each cartridge of 1.8 ml of solution for injection contains 54 mg of mepivacaine hydrochloride.
For the full list of excipients, see section 6.1.

4.4) Special warnings and precautions for use:
WARNINGS:
RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE IMMEDIATELY AVAILABLE. (See ADVERSE REACTIONS).
Reactions resulting in fatality have occurred on rare occasions with the use of local anesthetics, even in the absence of a history of hypersensitivity.
Fatalities may occur with use of local anesthetics in the head and neck region as the result of retrograde arterial flow to vital CNS areas even when maximum recommended doses are observed. The practitioner should be alert to early evidence of
alteration in sensorium or vital signs.
Methemoglobinemia: Cases of methemoglobinemia have been reported in association with local anesthetic use; Mepivacaine, along with other local anesthetics, is capable of producing this condition. Although all patients are at risk for methemoglobinemia, patients with glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, infants under 6 months of age, and concurrent exposure to oxidizing agents or their metabolites are more susceptible to developing clinical manifestations of the condition. If local anesthetics must be used in these patients, close monitoring for symptoms and signs of methemoglobinemia is recommended.
Signs of methemoglobinemia may occur immediately or may be delayed some hours after exposure, and are characterized by cyanosis of the skin, nail beds and lips, and/or abnormal coloration of the blood, fatigue and weakness. Methemoglobin levels may continue to rise; therefore, immediate treatment is required to avert more serious central nervous system and cardiovascular adverse effects, including seizures, coma, arrhythmias, and death. Discontinue mepivacaine and any other oxidizing agents. Depending on the severity of the signs and symptoms, patients may respond to supportive care, i.e., oxygen therapy, hydration. If methemoglobinemia does not respond to administration of oxygen, a more severe clinical presentation may require treatment with methylene blue exchange transfusion, or hyperbaric oxygen.

PRECAUTIONS:
The safety and effectiveness of mepivacaine depend upon proper dosage, correct technique, adequate precautions, and readiness for emergencies.
The lowest dose that results in effective anesthesia should be used to avoid high plasma levels and possible adverse effects. Injection of repeated doses of mepivacaine may cause significant increases in blood levels with each repeated dose due to slow accumulation of the drug or its metabolites, or due to slower metabolic degradation than normal.
Tolerance varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their weight and physical status. Mepivacaine should be used with caution in patients with a history of severe disturbances of cardiac rhythm or heart block.
INJECTIONS SHOULD ALWAYS BE MADE SLOWLY WITH ASPIRATION TO AVOID INTRAVASCULAR INJECTION AND THEREFORE SYSTEMIC REACTION TO LOCAL ANESTHETIC.
If sedatives are employed to reduce patient apprehension, use reduced doses, since local anesthetic agents, like sedatives, are central nervous system depressants which in combination may have an additive effect. Young children should be given minimal doses of each agent.
Changes in sensorium such as excitation, disorientation or drowsiness may be early indications of a high blood level of the drug and may occur following inadvertent intravascular administration or rapid absorption of mepivacaine. Local anesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.

Information for Patients/Patient Counseling Information:
The patient should be cautioned against loss of sensation and possibility of biting trauma should the patient attempt to eat or chew gum prior to return of sensation. Inform patients that use of local anesthetics may cause methemoglobinemia, a serious condition that must be treated promptly. Advise patients or caregivers to seek immediate medical attention if they or someone in their care experience the following signs or symptoms: pale, gray, or blue colored skin (cyanosis); headache; rapid heart rate; shortness of breath; lightheadedness; or fatigue.

קיימים עדכונים נוספים.
למידע נוסף יש לעיין בעלון לרופא המעודכן.
העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום
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