Orabloc Injection

Peripheral vasodilatation occurs, leading to decreased cardiac output and atrioventricular block, ventricular arrhythmias, and cardiac arrest, possibly at blood concentrations achieved with therapeutic doses of Orabloc. Changes in intravascular injection have been reported. These reactions may be due to intra-arterial administration of the local anesthetic with retrograde flow to the cerebral depression have been reported. These reactions may be due to intra-arterial injection that has been avoided.

However, that the absence of blood in the syringe does not guarantee that practitioners who employ local anesthetic agents including Orabloc should be aware of the risks associated with the use of these agents. These risks include severe asthmatic episodes in certain susceptible people. Sulte sensitivity is a rare condition that may occur in patients who are hypersensitive to products containing the local anesthetic in this class of drugs. Orabloc is contraindicated in patients who are hypersensitive to products containing articaine hydrochloride or epinephrine. For normal healthy adults, the maximum dose of articaine HCl (mg) should be based on the type of local anesthetic used and the duration of the procedure. The usual maximum dose of articaine HCl (mg) per procedure should not exceed 300 mg for patients weighing over 100 kg.

The use of articaine and the duration of use are necessary for the safe use of this product. The usual maximum dose of articaine HCl (mg) per procedure should not exceed 300 mg for patients weighing over 100 kg.

The usual maximum dose of articaine HCl (mg) per procedure should not exceed 300 mg for patients weighing over 100 kg.

For most routine dental procedures, Orabloc containing epinephrine 1:100,000 should be used. For oral surgery: 1 ml-5.1 mL (40 mg-204 mg articaine HCl) (2.1).

Articaine hydrochloride 4% (40 mg/mL) and epinephrine 1:100,000 (as epinephrine bitartrate 0.018 mg/mL) are contained in the injectable form of the solution. Orabloc should not be used in patients with cardiac or liver disease. (2.1)

Systemic toxicity of local anesthetics including Orabloc may be associated with convulsions and may be more likely to occur when large doses are given concomitantly with other agents having depressant effects on the CNS or heart, such as alcohol, sedative/hypnotics, general anesthetics, monoamine oxidase inhibitors, propoxyphene, or disulfiram. The most common adverse reaction of epinephrine is tachycardia and palpitations.

Orabloc should not be used in patients with ischemic heart disease: “Vasoconstrictor agents should be used in local anesthesia solutions during dental procedures in patients with cardiac disease. (5.3)

ANIMAL TOXICOLOGY/PHARMACOLOGY

Table 1: Recommended Dosages for Both Strengths

<table>
<thead>
<tr>
<th>Total dose of articaine HCl (mg)</th>
<th>Local anesthesia</th>
<th>Analgesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 mg</td>
<td>0.5 mL to 2.5 mL</td>
<td>20 mg to 100 mg</td>
</tr>
<tr>
<td>80 mg</td>
<td>1 mL to 5 mL</td>
<td>40 mg to 200 mg</td>
</tr>
<tr>
<td>120 mg</td>
<td>2 mL to 10 mL</td>
<td>80 mg to 400 mg</td>
</tr>
<tr>
<td>160 mg</td>
<td>3 mL to 15 mL</td>
<td>120 mg to 600 mg</td>
</tr>
</tbody>
</table>

Pharmacodynamic effects

Cardiovascular: Adverse reactions observed in at least 1% of patients:

- Headache
- Hypertension
- Tachycardia
- Hypotension
- Palpitations
- Vomiting
- Nausea

Respiratory: Adverse reactions observed in at least 1% of patients:

- Dizziness
- Fatigue
- Irritability
- Dyspnea
- Nausea

Gastrointestinal: Adverse reactions observed in at least 1% of patients:

- Paresthesia
- Altered taste
- Diarrhea
- Constipation

Central Nervous System: Adverse reactions observed in at least 1% of patients:

- Dizziness
- Fatigue
- Irritability
- Ataxia

BENEFITS AND RISKS

Orabloc may be associated with convulsions and may be more likely to occur when large doses are given concomitantly with other agents having depressant effects on the CNS or heart, such as alcohol, sedative/hypnotics, general anesthetics, monoamine oxidase inhibitors, propoxyphene, or disulfiram. Systemic effects of local anesthetics may cause excessive amounts of local anesthetic are absorbed systemically.

May be associated with convulsions and may be more likely to occur when large doses are given concomitantly with other agents having depressant effects on the CNS or heart, such as alcohol, sedative/hypnotics, general anesthetics, monoamine oxidase inhibitors, propoxyphene, or disulfiram. Systemic effects of local anesthetics may cause excessive amounts of local anesthetic are absorbed systemically.

May be associated with convulsions and may be more likely to occur when large doses are given concomitantly with other agents having depressant effects on the CNS or heart, such as alcohol, sedative/hypnotics, general anesthetics, monoamine oxidase inhibitors, propoxyphene, or disulfiram. Systemic effects of local anesthetics may cause excessive amounts of local anesthetic are absorbed systemically.

May be associated with convulsions and may be more likely to occur when large doses are given concomitantly with other agents having depressant effects on the CNS or heart, such as alcohol, sedative/hypnotics, general anesthetics, monoamine oxidase inhibitors, propoxyphene, or disulfiram. Systemic effects of local anesthetics may cause excessive amounts of local anesthetic are absorbed systemically.
assisted or controlled ventilation as needed. The adequacy of the circulation is evaluated by monitoring the patient’s state of consciousness after each local anesthetic injection. At the first signs of circulatory distress, adequate doses of ephedrine are administered. In patients with peripheral arterial disease, arterial blood pressure trends are carefully monitored throughout the procedure and anginal pain is treated immediately.

8.6 Renal/Hepatic Insufficiency

Doses of articaine HCl have been safely administered to 4 patients for complex procedures. In clinical trials, 54 patients between the ages of 65 and 75 years, and 11 patients 75 years of age or older who required additional injections. Of the 11 patients 75 years of age or older who required additional injections of articaine HCl, doses from 0.78 mg/kg to 4.76 mg/kg (1.3 mL to 11.9 mL) of articaine HCl were administered safely to 7 patients for simple procedures and 0.80 mg/kg to 5.48 mg/kg (1.3 mL to 11.9 mL) of articaine HCl were administered safely to 4 patients for complex procedures.

In pre- and postnatal developmental studies subcutaneous administration of articaine HCl to newborn rats at doses of 0.3 cm-0.4 cm for simple procedures and 0.5 cm-0.6 cm for complex procedures. No deaths occurred. No evidence of increased fetal deaths and increased fetal skeletal variations, but these effects may be related to operator error.

The administration of local anesthetic solutions containing epinephrine to pregnant women may result in fetal death, placental abruption, or other complications. In a study using articaine and epinephrine (1:100,000) rather than articaine hydrochloride alone produced maternal toxicity, but no effects on offspring. Study using articaine and epinephrine (1:100,000) in pregnant women resulted in maternal toxicity, but no effects on offspring.

The following adverse reactions have been identified during postapproval use of Orabloc: In over 1000 patients, but greater sensitivity of some older individuals cannot be ruled out. In over 1000 patients, but greater sensitivity of some older individuals cannot be ruled out. In over 1000 patients, but greater sensitivity of some older individuals cannot be ruled out. In over 1000 patients, but greater sensitivity of some older individuals cannot be ruled out.

Table 3: Adverse Reactions in Controlled Trials with an Incidence of Less than 1% but Considered Clinically Relevant

<table>
<thead>
<tr>
<th>Event</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System</td>
<td></td>
</tr>
<tr>
<td>Asthenia</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td>Back pain</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Pain</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Headache</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Ear pain</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Taste perversion</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Sinus pain</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Osteomyelitis</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Acute rhinitis</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Acute sinusitis</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Adverse Reactions Observed in Less than 1% of Patients:

- Numbness and tingling
- Anaphylactoid reaction
- Injection site reaction
- Positive blood aspiration
- Pain
- Any adverse event

As with all local anesthetics, these reactions may be severe and require prompt medical attention. These postmarketing events have been reported chiefly following nerve blocks. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable.

Adverse Reactions Observed in Less than 1% of Patients:

- Numbness and tingling
- Injection site reaction
- Positive blood aspiration
- Pain
- Any adverse event

These postmarketing events have been reported chiefly following nerve blocks. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable. In patients with a history of allergy to the compound used for the nerve block, premedication is advisable.