DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
Tetracaine hydrochloride is a local anesthetic of the ester-linkage type, related to procaine.

1% Solution: A sterile, isotonic, isobaric solution.

Each mL contains:

Active: 10 mg Tetracaine Hydrochloride

Inactives: 0.75 mg Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (3.2 to 6.0) and Water for Injection, USP. Nitrogen gas has been used to displace the air in the ampules.

This formulation does not contain preservatives.

CLINICAL PHARMACOLOGY

Parenteral administration of tetracaine hydrochloride stabilizes the neuronal membrane and prevents initiation and transmission of nerve impulses thereby effecting local anesthesia. The onset of action is rapid, and the duration is prolonged (up to two or three hours or longer of surgical anesthesia).

The safety and effectiveness of any spinal anesthetic depend upon proper dosage, correct technique, adequate precautions, and readiness for emergencies. The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious systemic side effects. Tolerance varies with the status of the patient; debilitated, elderly patients or acutely ill patients should be given reduced doses commensurate with their weight, age, and physical status. Reduced doses are also indicated for obstetric patients and those with increased intra-abdominal pressure.

Drug Interactions: Tetracaine hydrochloride should not be used if the patient is being treated with a sulfonamide because aminobenzoic acid inhibits the action of sulfonamides.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: There have been no long-term animal studies to evaluate carcinogenic potential and reproduction studies in animals. There is no evidence from human data that tetracaine hydrochloride may be carcinogenic or that it impairs fertility. Pregnancy Category C: There have been no animal reproduction studies conducted with tetracaine hydrochloride. It is not known whether tetracaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Tetracaine hydrochloride should be given to a pregnant woman only if clearly needed and the potential benefits outweigh the risk.

Nursing Mothers: It is not known whether tetracaine hydrochloride is excreted in human milk; however, it is rapidly metabolized following absorption into the plasma. Because many drugs are excreted in human milk, caution should be exercised when tetracaine hydrochloride is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of tetracaine hydrochloride in pediatric patients have not been established.

ADVERSE REACTIONS

Systemic adverse reactions to tetracaine hydrochloride are characteristic of those associated with other local anesthetics and can involve the central nervous system and the cardiovascular system.
Systemic reactions usually result from high plasma levels due to excessive dosage, rapid adsorption, or inadvertent intravascular injection.

A small number of reactions to tetracaine hydrochloride may result from hypersensitivity, idiosyncrasy, or diminished tolerance to normal dosage.

Central nervous system effects are characterized by excitation or depression. The first manifestation may be nervousness, dizziness, blurred vision, or tremors, followed by drowsiness, convulsions, unconsciousness and possibly respiratory and cardiac arrest. Since excitement may be transient or absent, the first manifestation may be drowsiness, sometimes merging into unconsciousness and respiratory and cardiac arrest. Other central nervous system effects may be nausea, vomiting, chills, confusion of the pupils, or titiitus.

Cardiovascular system reactions include depression of the myocardium, blood pressure changes (usually hypotension), and cardiac arrest.

Allergic reactions, which may be due to hypersensitivity, idiosyncrasy, or diminished tolerance, are characterized by cutaneous lesions (e.g., urticaria), edema, and other manifestations of allergy. Detection of sensitivity by skin testing is of limited value. Severe allergic reactions including anaphylaxis have rarely occurred and are not usually dose-related.

Reactions Associated with Spinal Anesthesia Techniques: Central Nervous System: Post-spinal headache, meningismus, arachnoiditis, palsies, or spinal nerve paralysis. Cardiovascular: hypotension due to vasomotor paralysis and pooling of the blood in the venous bed. Respiratory: respiratory impairment or paralysis due to the level of anesthesia extending to the upper thoracic and cervical segments. Gastrointestinal: nausea and vomiting.

Treatment of Reactions: Toxic effects of local anesthetics require symptomatic treatment; there is no specific cure. The most important measure is oxygenation of the patient by maintaining an airway and supporting ventilation. Supportive treatment of the cardiovascular system includes intravenous fluids and, when appropriate, vasopressors (preferably those that stimulate the myocardium). Convulsions are usually controlled with adequate oxygenation alone but intravenous administration in small increments of a barbiturate (preferably an ultrashort-acting barbiturate such as thiopental and thiamylal), or diazepam can be utilized. Intravenous barbiturates or anticonvulsant agents should only be administered by those familiar with their use and only if ventilation and oxygenation have first been assured. In spinal anesthesia, sympathtic blockade also occurs as a pharmacological action, resulting in peripheral vasodilation and often hypotension. The extent of the hypotension usually depend on the number of dermatomes blocked. The blood pressure should therefore be monitored in the early phases of anesthesia. If hypotension occurs, it is readily controlled by vasodilators administered either by the intramuscular or the intravenous route, the dosage of which would depend on the severity of the hypotension and the response to treatment.

Dosage and Administration

As with all anesthetics, the dosage varies and depends upon the area to be anesthetized, the number of neuronal segments to be blocked, individual tolerance, and the technique of anesthesia. The lowest dosage needed to provide effective anesthesia should be administered. For specific techniques and procedures, refer to standard textbooks.

Suggested Dosage for Spinal Anesthesia Using 1% Tetracaine HCl Injection, USP

<table>
<thead>
<tr>
<th>Extent of Anesthesia</th>
<th>Dose of solution (mL)</th>
<th>Volume of spinal fluid (mL)</th>
<th>Site of injection (lumbar interspace)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perineum</td>
<td>0.5 (= 5 mg)*</td>
<td>0.5</td>
<td>4th</td>
</tr>
<tr>
<td>Perineum and lower extremities</td>
<td>1.0 (= 10 mg)</td>
<td>1.0</td>
<td>3rd or 4th</td>
</tr>
<tr>
<td>Up to costal margin</td>
<td>1.5 to 2.0 (= 15 mg to 20 mg)†</td>
<td>1.5 to 2.0</td>
<td>2nd, 3rd, or 4th</td>
</tr>
</tbody>
</table>

* For vaginal delivery (saddle block), from 2 mg to 5 mg in dextrose.
† Doses exceeding 15 mg are rarely required and should be used only in exceptional cases. Inject solution at rate of about 1 mL per 5 seconds.

The extent and degree of spinal anesthesia depend upon dosage, specific gravity of the anesthetic solution, volume of solution used, force of the injection, level of puncture, position of the patient during and immediately after injection, etc.

When spinal fluid is added to 1% tetracaine hydrochloride injection, some turbidity results, the degree depending on the pH of the spinal fluid, the temperature of the solution during mixing, as well as the amount of drug and diluent employed. Liberation of base (which is completed within the spinal canal) is held to be essential for satisfactory results with any spinal anesthetic.

The specific gravity of spinal fluid at 25°C to 25°C varies under normal conditions from 1.0063 to 1.0075. The 1% concentration in saline solution has a specific gravity of 1.0080 to 1.0074 at 25°C to 25°C. A hyperbaric solution may be prepared by mixing equal volumes of the 1% solution and Dextrose Solution 10%.

Examine ampules carefully before use. Do not use solution if crystals, cloudiness, or discoloration is observed.

This formulation of tetracaine hydrochloride does not contain antimicrobial or bacteriostatic agents; therefore, unused portions should be discarded.

Stabilization of Ampules

The tetracaine hydrochloride injection is sterile within an undamaged ampule. To destroy bacteria on the exterior of ampules use heat sterilization (autoclaving) before opening. Immersion in antiseptic solution is not recommended.

Autoclave at 15-pounds pressure, at 121°C (250°F), for 15 minutes.

Autoclaving increases likelihood of crystal formation. Unused autoclaved ampules should be discarded. Under no circumstances should unused ampules which have been autoclaved be returned to stock.

HOW SUPPLIED

1% isotonic isobaric solution: 2 mL Ampules, box of 25.
NDC 17478-045-32

Storage: Store under refrigeration. Protect ampules from light.