DESCRIPTION: Mepivacaine hydrochloride is 2-Piperidine-carboxamide, N-[2-ethylidene-dimethyl-phenyl]-1-methyl- monohydrochloride and has the following structural formula:

\[
\text{CH}_3 \begin{array}{c}
\text{N} \\
\text{CONH} \end{array} \cdot \text{HCl}
\]

It is a white, crystalline, odorless powder, soluble in water, but very resistant to both acid and alkaline hydrolysis.

Mepivacaine hydrochloride is a local anesthetic available as sterile isotonic solutions (clear, colorless) in concentrations of 1%, 1.5% and 2% for injection via local infiltration, peripheral nerve block, and caudal and lumbar epidural blocks.

Mepivacaine hydrochloride is related chemically and pharmacologically to the amide-type local anesthetics. It contains an amide linkage between the aromatic nucleus and the amino group.

Composition of Available Solutions*:

<table>
<thead>
<tr>
<th>Percentage of Total Vial</th>
<th>Vial Vial Vial Vial Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>1.5%</td>
<td>1.5%</td>
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<tr>
<td>2%</td>
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<td>3%</td>
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<tr>
<td>15%</td>
<td>15%</td>
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<tr>
<td>20%</td>
<td>20%</td>
</tr>
</tbody>
</table>

*Vial Vial Vial Vial Vial

Vial Vial Vial Vial Vial

Mepivacaine hydrochloride 10 10 15 20 20
Sodium chloride 6.6 7 5.6 4.6 5
Potassium chloride 0.3 0.3 0.3 0.3
Calcium chloride 0.33 0.33 0.33 0.33
Methylparaben 1 1

The pH of the solution is adjusted between 4.5 and 6.8 with sodium hydroxide or hydrochloric acid.

CLINICAL PHARMACOLOGY:

Local anesthetics block the generation and the conduction of nerve impulses, presumably by altering the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential. In general, the progression of anesthesia is related to the diameter, myelination, and conduction velocity of the affected nerve fibers. Clinically, the order of loss of nerve function is as follows: pain, temperature, touch, proprioception, and skeletal muscle tone.

Systemic absorption of local anesthetics produces effects on the cardiovascular and central nervous systems. Local anesthetics achieve with normal therapeutic doses, changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance are minimal. However, toxic blood concentrations depress cardiac conduction and excitability, which may lead to atrioventricular block and ultimately to cardiac arrest. In addition, myocardial contractility is depressed at peripheral concentrations occur. The degree of cardiac output and arterial blood pressure is influenced by the rate of systemic absorption and the degree of peripheral vasoconstriction.

Following systemic absorption, local anesthetics can produce central nervous system stimulation, depression, or both. Apparent central stimulation is manifested as restlessness, tremors, and shivering, progressing to convulsions, followed by depression and coma progressing ultimately to respiratory arrest. However, the local anesthetics have a primary depressant effect on the medulla and on higher centers. The depressed stage may occur without a prior excited stage.

A clinical study using 15 mL of 2% epidural mepivacaine in 161 patients, 19 to 75 years of age, demonstrated a 40% decrease in the amount of mepivacaine required to block a given number of dermatomes in the elderly (60 to 79 years, N=13) as compared to young adults 20 to 39 years.

Another study using 10 mL of 2% lumbar epidural mepivacaine in 161 patients, 19 to 75 years of age, demonstrated a strong inverse relationship between patient age and the number of dermatomes blocked per cc of mepivacaine injected.

Pharmacokinetics:

The rate of systemic absorption of local anesthetics is dependent upon the total dose and concentration of drug administered, the route of administration, the vascularity of the administration site, and the presence or absence of epinephrine in the anesthetic solution. A dilute concentration of epinephrine (1:200,000 or 5 mcg/mL) usually reduces the rate of absorption and plasma concentration of mepivacaine, however, it has been reported that vasoconstrictors do not significantly prolong anesthesia with mepivacaine.

Onset of anesthesia with mepivacaine is rapid, the time of onset for sensory block ranging from about 3 to 20 minutes depending upon such factors as the anesthetic technique, the type of block, the concentration of the solution, and the individual patient. The degree of motor blockade produced is dependent on the concentration of the solution. A 0.5% solution will be effective in small superficial nerve blocks while the 1% concentration will block sensory and sympathetic conduction without loss of motor function. The 1.5% solution will provide extensive and often complete motor block and the 2% concentration of mepivacaine hydrochloride will produce complete sensory and motor block of any nerve group.

The duration of anesthesia also varies depending upon the technique and type of block, the concentration, and the individual. Mepivacaine will normally provide anesthesia which is adequate for 2 to 2 1/2 hours of surgery.

Local anesthetics are bound to plasma proteins in varying degrees. Generally, the lower the plasma concentration of drug, the higher the percentage of drug bound to plasma.

Local anesthetics appear to cross the placenta by passive diffusion. The rate and degree of diffusion is governed by the degree of plasma protein binding, the degree of ionization, and the degree of lipid solubility. Fetal/maternal ratios of local anesthetics appear to be inversely related to the degree of plasma protein binding, because only the free, unbound drug is available for placental transfer. Mepivacaine is approximately 75% bound to plasma proteins. The extent of placental transfer is also determined by the degree of ionization and lipid solubility of the drug. Lipid soluble mepivacaine nonionized drugs readily enter the fetal blood from the maternal circulation.

Depending upon the route of administration, local anesthetics are distributed to some extent to all body tissues, with high concentrations found in highly perfused organs such as the liver, lungs, heart, and brain.

Various pharmacokinetic parameters of the local anesthetics can be significantly altered by the presence of hepatic or renal disease, addition of epinephrine, factors affecting urinary pH, renal blood flow, the route of drug administration, and the age of the patient. The half-life of mepivacaine in adults is 1.9 to 3.2 hours and in neonates 8.7 to 9 hours.

Mepivacaine, because of its amide structure, is not detoxified by the circulating plasma esterases. It is rapidly metabolized, with only a small percentage of the anesthetic (5 percent to 10 percent) being excreted unchanged in the urine. The liver is the principal site of metabolism, with over 50% of the administered dose being excreted into the bile as metabolites. Most of the metabolized mepivacaine is probably resorbed intact and then excreted into the urine since only a small percentage is found in the feces. The principal route of excretion is via the kidney. Most of the anesthetic and its metabolites are eliminated within 30 hours. Routine drug monitoring has established with regard to intrathecal injection, either intentionally or inadvertently, of such preparations of the triptyline or imipramine types, monoamine oxidase inhibitors (MAOI) or antidepressants of the amide-type or to other compounds discussed in pediatric and adult patients following epidural anesthesia, but no cases of gleno-humeral chondrolysis have been described in pediatric and adult patients following epidural, paracervical, caudal blocks. Currently, there is no effective treatment for chondrolysis. Marketing reports of chondrolysis in patients receiving monoamine oxidase inhibitors or other antidepressants including mepivacaine to evaluate the carcinogenic potential have not been conducted.

The injection procedures require the utmost care. It is recommended that a test dose be administered without epinephrine for periods of 48 to 72 hours. Patient monitoring is essential.

Intraspinal injection is still possible even if continuous (intermittent) catheter techniques. An expulsive effort is necessary after the injection to avoid intravascular injection.

Early unexplained signs of tachycardia, tachypnea, and respiratory distress should be used to avoid high plasma levels during the injection to avoid intravascular injection.

During the injection to avoid intravascular injection, the injection should be stopped immediately when it is felt that the needle tip may be in the subarachnoid space. In such instances, the patient should be observed closely, and resuscitation equipment, and the personnel which might arise from the block to be employed should be at hand. When the clinical conditions permit, an effective resuscitation mixture should be immediately available. Dosages should be calculated with constant attention to the patient, and serious adverse effects. Injections should be taken into account.

INDICATIONS AND USAGE:

POLOCAINE® (Mepivacaine HCl Injection, USP), POLOCAINE®-MPF (Mepivacaine Hydrochloride Injection, USP) are indicated for production of local or regional anesthesia or analgesia by the following methods: epidural or subarachnoid injection.

The routes of administration and indicated concentrations for mepivacaine are:

- **Local infiltration:** 0.5% (via dilution) or 1%
- **Peripheral nerve blocks:** 1% and 2%
- **Epidural block:** 1%, 1.5%, 2%
- **Caudal block:** 1%, 1.5%, 2%

See DOSAGE AND ADMINISTRATION for additional information. Standard textbooks should be consulted to determine the accepted procedures and techniques for the administration of mepivacaine.

**POLOCAINE® POLOCAINE®-MPF Rx only**

**POLOCAINE® POLOCAINE®-MPF**

These solutions are not intended for spinal anesthesia or dental use.
CONTRAINDICATIONS: Mepivacaine is contraindicated in patients with a known sensitivity to it or to any local anesthetic of the amide-type or to other components of mepivacaine solutions.

WARNINGS: LOCAL ANESTHETICS SHOULD ONLY BE EMPLOYED BY CLINICIANS WHO ARE WELL VERSED IN THEIR USE AND WHOSE SKILL AND REFERENCES ARE BROAD ENOUGH TO INCLUDE RELEVANT EMERGENCIES. USES ONLY WHEN SAFELY AND EFFECTIVELY USED MAY EXPECT TO RECEIVE THE IMMEDIATE AVAILABILITY OF OXYGEN, OTHER RESUSCITATIVE DRUGS, CARDIOPULMONARY RESUSCITATION AND THE PROPER RESOURCES NEEDED FOR PROPER MANAGEMENT OF TOXIC REACTIONS AND RELATED EMERGENCIES (see IMPORTANT PRECAUTIONS). DELAY IN PROPER MANAGEMENT OF DISEASE-RELATED TOXICITY, UNDERVENTILATION FROM ANY CAUSE, AND/OR RESPIRATORY ARREST AND THE DEVELOPMENT OF ACIDOSIS, CARDIAC ARREST AND, POSSIBLY, DEATH.

Local anesthetic solutions containing antimicrobial preservatives (ie, those supplied in multiple-dose vials) should not be used for epidural or caudal anesthesia. This has not been established with regard to intrathecal injection, either intentionally or inadvertently, of such preservatives. Intra-articular infusions of local anesthetics following arthroscopic and other surgical procedures is indicated, and there have been post-marketing reports of chordalopathy in patients receiving such infusions. The majority of reported cases of chordalopathy involved the shoulder; however, cases of glenohumeral chordalopathy have been described in pediatric and adult patients following intrathecal or local anesthetic administration without epinephrine for periods of 48 to 72 hours. There is insufficient information to determine whether such late onset periods are associated with these findings. The time of onset of symptoms, such as joint pain, stiffness and loss of motion can be variable, but may occur as early as the 2nd or 3rd month after surgery. Currently, there is no effective treatment for chordalopathy; therefore, patients who have experienced chordalopathy have required additional diagnostic and therapeutic procedures and some required arthroplasty or shoulder replacement surgery.

It is essential that aspiration for blood or cerebrospinal fluid (where applicable) be done prior to injecting local anesthetic, both the original dose and all subsequent doses, to avoid intravascular or subarachnoid injection. However, a negative aspiration does not ensure against an intravascular or subarachnoid injection. Reactions resulting in fatality have occurred on rare occasions with the use of local anesthetics.

Mepivacaine with epinephrine or other vaso-pressors should not be used concomitantly with each other. Because of the potential for serious hypertensive or cardiovascular reactions, these agents should generally be avoided. In situations where vasoconstriction is required, much lower doses of mepivacaine solutions should also be performed before and during each supplemental injection in continuous (intermittent) catheter techniques. An intravascular injection is still possible even if aspirations for blood are negative.

During the administration of epidural anesthesia, it is recommended that a test dose be administered initially to the first patient so that the full dose is given. When using a “continuous” catheter technique, test doses should be given prior to both the test dose and any succeeding doses, because plastic tubing in the epidural space can migrate into a blood vessel or through the dura. When the clinical effectiveness of an effective test dose should contain epinephrine (10 mcg to 15 mcg have been suggested) to serve as a warning of unintended intravascular injection. If injected into a blood vessel, the amount of epinephrine is likely to produce an “epinephrine response” within 45 seconds, consisting of pulse and blood pressure, circumbacterial pallor, palpitations, and nervousness in the unselected patient. The sedated patient may exhibit an initial rise of blood pressure or more beats per 15 or more seconds. Therefore, following the test dose, the heart rate should be monitored for a heart rate increase. The test dose should also contain 45 mg to 50 mg of mepivacaine to detect an unintended intrathecal administration. This will be evidenced within a few minutes by signs of spinal block (eg, decreased sensation of the buttocks, paresis of the legs, or, in the sedated patient, absent knee jerk).

Incorporated test doses of local anesthetics may cause significant increases in plasma levels with each repeated dose due to slow accumulation of the drug or its metabolites or to slow metabolic degradation. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients or patients who should be given reduced doses commensurate with their age and physical status. Local anesthetics should also be used with caution in patients with severe disease of the cardiovascular system, shock, heart block, or hypotension. Careful and constant monitoring of cardiovascular and respiratory (adequacy of ventilation) vital signs, and the patient’s state of consciousness should be performed periodically. While the use of local anesthetic injection. It should be kept in mind at such times that restlessness, anxiety, incoherent speech, light-headedness, and tingling of the mouth and limbs, metallic taste, tinnitus, dizziness, blurred vision, tremors, twitching, depression, or drowsiness may be signs of central nervous system toxicity.

Local anesthetic solutions containing a vasoconstrictor should be used cautiously and in carefully restricted quantities in areas of the body supplied by end arteries or having otherwise compromised blood supply such as digits, nose, external ear, penis. Patients with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Mepivacaine should be used with caution in patients with known allergies and sensitivities. Because amide-type local anesthetics such as mepivacaine are metabolized by the liver and excreted in the urine, pregnant women may be more sensitive to the effects of local anesthetic. Therefore, patients with severe hepatic insufficiency or renal disease, or those with a history of markedly decreased blood supply such as digits, nose, external ear, penis may be more sensitive to the effects of local anesthetic. Therefore, patients with severe hepatic insufficiency or renal disease, or those with a history of markedly decreased blood supply may exhibit exaggerated vasoconstrictor response. Ischemic injury or necrosis may result. Mepivacaine should be used with caution in patients with impaired cardiovascular function because they may be less able to compensate for changes associated with the prolongation of AV conduction produced by these drugs.

Serious dose-related cardiac arrhythmias may occur if preparations containing a vasoconstrictor such as epinephrine are employed in patients who develop and administer a potent ion channel anesthetic. In deciding whether to use a vasoconstrictor concurrently with the same patient, the combined action of both agents upon the myocardium, the concentration and volume of vasoconstrictor used, and the time since injection, when applicable, should be taken into account. Many drugs, during the conduct of anesthesia are considered potential triggering agents for familial malignant hypertension. Because it is not known whether concomitant use of local anesthetics may trigger this reaction and because the need for supplemental general anesthesia cannot be predicted in all instances, it is recommended that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, labile blood pressure or other signs of cardiac toxicity may precipitate temperature elevation. Successful outcome is dependent on early diagnosis, prompt dis continuance of medications (including agent(s), and institution of treatment, including oxygen therapy, indicated supportive measures, and diuretics.

(Consult dantrolene sodium intravenous package insert for use.)
The use of some local anesthetic drug products during labor and delivery may be followed by unpleasant muscle stiffness and tone for the first day or two of life. The long-term significance of these observations is unknown. A fetal death may occur in 5 to 30 percent of patients receiving paracervical block anesthesia with the amide-type local anesthetics and may be related to acute fetal acidosis. Fetal death should always be monitored during paracervical anesthesia. Added risk appears to be present in patient with pre-eclampsia, placental insufficiency, toxemia of pregnancy, and fetal distress. The physician should weigh the possible advantages against dangers when considering the use of the paracervical block. Careful adherence to recommended dosage is of the utmost importance in obstetrical paracervical anesthesia. Inadequate analgesia with recommended doses may result in unnecessary extra intravenous excretion of the local anesthetic has been used successfully to manage the mother’s pain.

Case reports of maternal convulsions and cardiovascular collapse following use of some local anesthetics have been reported. The route of administration (as for elective abortion) suggest that systemic absorption under these circumstances may be low, and the developed maximum dose of the local anesthetic should not be exceeded. Injection should be made slowly and with frequent aspiration. Allow a five-minute interval between sides.

It is extremely important to avoid aortocaval compression during epidural anesthesia (see “Geriatric Use” and the section “Precautions”) to prevent respiratory distress and hypotension (or sometimes hyper- tension), bradycardia, ventricular arrhythmias, and possibly cardiac arrest (see WARNINGS, PRECAUTIONS, and OVERDOSAGE).

Allergic Allergic-type reactions are rare and may occur as a result of sensitivity to the local anesthetic or to other formulation ingredients, such as the antimicrobial preservative methylparaben, contained in multiple-dose vials. These reactions are characterized by signs such as urticaria, pruritis, erythema, and angioedema (including laryngeal edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, edema (facial, truncal, and possibly, anaphylactoid-like symptomatology (including severe hypotension and vasovagal activity among members of the amide-type local anesthetic group has been reported. The usefulness of screening for sensitivity has not been definitely established.

Neurologic The incidences of adverse neurologic reactions associated with the use of local anesthetics may be related to the total dose of local anesthetic administered and are also dependent upon the particular drug used, the route of administration, and the physical status of the patient. Many of these effects may be related to local anesthetic techniques, with or without a contribution from the drug. In the practice of caudal or lumbar epidural block, occasional unintentional penetration of the subarachnoid space with local anesthetic and air or blood or needle may occur. Subsequent adverse effects may depend partially on the amount of drug administered intrathecally and the total volume and physical effects of a dural puncture. A high spinal is characterized by paralyzation of the legs, loss of consciousness, respiratory paralysis, and death. Neurologic effects following epidural or caudal anesthesia may include spinal block of varying magnitude (including high or total spinal block); hypotension secondary to spinal block; urinary retention; fecal and urinary incontinence; loss of perineal sensation and sexual function; persistent anesthesia, paresthesia, weakness, paralysis of the lower extremities, and loss of sphincter control all of which may have slow, incomplete, or no recovery; headache; backache; septic meningitis; meningismus, slowing of labor; increased incidence of forceps delivery; cranial nerve palsies due to traction on nerves from loss of cerebrospinal fluid. Neurologic effects following other procedures or routes of administration may include persistent anesthesia, paresthesia, weakness, paralysis, all of which may have slow, incomplete, or no recovery.

OVERDOSAGE: Acute emergencies from local anesthetics are generally related to high plasma levels encountered during the administration of local anesthetics or to unintended subarachnoid injection of local anesthetic solution (see ADVERSE REACTIONS, WARNINGS, and Management of Local Anesthetic Emergencies). The first consideration is prevention, best accomplished by careful dosage calculation and by the use of a monitoring system (including central venous pressure and central hemodynamics). In the event of systemic toxicity, hypotension, and possibly cardiac arrest may occur. The usefulness of screening for sensitivity has not been definitely established.

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approved for this use (see WARNINGS and DOSAGE AND ADMINISTRATION).

The recommended single adult dose (or the total of a series of doses given in one procedure) of mepivacaine hydrochloride for unseated, healthy, normal-sized individuals should not usually exceed 400 mg. The recommended dosage is based on requirements for the average adult and should be reduced for elderly or debilitated patients. While maximum doses of 7 mg/kg (550 mg) have been administered without adverse effect, these are not recommended, except in exceptional circumstances and under no circumstances should the administration be repeated at intervals of less than 1½ hours. The total dose for any 24-hour period should not exceed 1,000 mg because of a slow accumulation of the anesthetic or its derivatives or slower than normal metabolic degradation or detoxification with repeat administration (see CLINICAL PHARMACOLOGY and PRECAUTIONS).

Pediatric patients tolerate the local anesthetic as well as adults. However, the pediatric dose should be carefully measured as a percentage of the total adult dose based on weight, and should not exceed 5 mg/kg to 6 mg/kg (2.5 mg/lb to 3 mg/lb) in pediatric patients, especially those weighing less than 30 lbs. In pediatric patients under 3 years of age or weighing less than 30 lbs concentrations less than 2% (eg, 0.5% to 1.5%) should be employed.

Unused portions of solutions not containing preservatives, ie, those supplied in single-dose vials, should be discarded following initial use. This product should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Solutions which are discolored or which contain particulate matter should not be administered.

### Recommended Concentrations and Doses of Mepivacaine Hydrochloride

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Concentration</th>
<th>Total Dose</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conical block</td>
<td>1%</td>
<td>5 to 40</td>
<td>50 to 400 Potential block one half of total dose injected each side</td>
</tr>
<tr>
<td>Intercostal, paravertebral nerve block</td>
<td>2%</td>
<td>5 to 20</td>
<td>100 to 400</td>
</tr>
<tr>
<td>Transversal block</td>
<td>1%</td>
<td>up to 30</td>
<td>up to 300 One half of total dose injected each side. See PRECAUTIONS</td>
</tr>
<tr>
<td>(lumbosacral) (sciatic) (paravertebral) (pudendal)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pudendal block</td>
<td>1%</td>
<td>up to 20</td>
<td>up to 200 One half of total dose injected each side. This is maximum recommended dose per 90-minute period in obstetrical and non-obstetrical patients. Inject slowly, 5 minutes between sides. See PRECAUTIONS</td>
</tr>
<tr>
<td>Caudal and Epidural block</td>
<td>1% 1.3%</td>
<td>15 to 30</td>
<td>150 to 300 *Use only single-dose vials which do not contain a preservative</td>
</tr>
<tr>
<td></td>
<td>2%</td>
<td>10 to 25</td>
<td>150 to 260</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200 to 400</td>
<td></td>
</tr>
<tr>
<td>Infiltration</td>
<td>1%</td>
<td>up to 40</td>
<td>up to 400 An equivalent amount of 0.5% solution prepared by diluting the 1% solution with Sodium Chloride Injection, USP may be used for large areas.</td>
</tr>
<tr>
<td>Therapeutic block (pain management)</td>
<td>1% 2%</td>
<td>1 to 5</td>
<td>10 to 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 to 5</td>
<td>20 to 100</td>
</tr>
</tbody>
</table>

* Dosage forms listed as POLOCAINE-MPF (Mepivacaine HCl Injection, USP) are single-dose solutions which do not contain a preservative.

**HOW SUPPLIED:**

Single-dose vials and multiple-dose vials of POLOCAINE may be sterilized by autoclaving at 15 pound pressure, 121°C (250°F) for 15 minutes. Solutions of POLOCAINE may be reautoclaved when necessary. Do not administer solutions which are discolored or which contain particulate matter.

**THESE SOLUTIONS ARE NOT INTENDED FOR SPINAL ANESTHESIA OR DENTAL USE.**

**POLOCAINE-MPF (Mepivacaine HCl Injection, USP) without preservatives is available as follows:**

<table>
<thead>
<tr>
<th>Product No.</th>
<th>NDC No.</th>
<th>Strength</th>
<th>Vial Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>50037</td>
<td>03323-260-37</td>
<td>1% (10 mg/mL)</td>
<td>30 mL single dose vial, packaged in trays of 25.</td>
</tr>
<tr>
<td>29037</td>
<td>03323-293-37</td>
<td>1.5% (15 mg/mL)</td>
<td>30 mL single dose vial, packaged in trays of 25.</td>
</tr>
<tr>
<td>29027</td>
<td>03323-294-27</td>
<td>2% (20 mg/mL)</td>
<td>30 mL single dose vial, packaged in trays of 25.</td>
</tr>
</tbody>
</table>

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]; brief exposure up to 40°C (104°F) does not adversely affect the product.

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