

BRETYLIUM TOSYLATE INJECTION, USP ORDERING INFORMATION

Description:

Each milliliter contains 50 mg bretylium tosylate in water for injection

How Supplied:

Each single-dose vial is supplied as 500 mg/10 mL (contains no preservative) for IM or IV

Unit of Sale: 1 vial

NDC Number: 62559-870-11

Weight and Dimensions:

Weight of vial and carton: 30.9 g

Dimensions of vial carton: 1 ¼" x 1 ¼" x 2 ½" (LxWxH)

Storage: Store at 20° to 25°C (68° to 77°F);
[see USP Controlled Room Temperature]

Usage:

The minimum vial usage for one patient is (1) vial and a maximum of (4) vials per day.
The average patient will use (2) vials in a day.



Distribution and Order Information

Order Number	Distributor	Customer Service Number
10232217	AmerisourceBergen	1-844-222-2273
5587472	Cardinal Health	1-800-926-3161
3493533	McKesson	1-855-625-4677

Please see Brief Summary of Prescribing Information on next page.

Distributed by:

ANI Pharmaceuticals, Inc.
Baudette, MN 56623

Indications and Usage

Bretylium Tosylate Injection, USP is indicated in the prophylaxis and therapy of ventricular fibrillation.

Bretylium Tosylate Injection, USP is also indicated in the treatment of life-threatening ventricular arrhythmias, such as ventricular tachycardia that have failed to respond to adequate doses of a first-line antiarrhythmic agent, such as lidocaine.

Use of Bretylium Tosylate Injection, USP should be limited to intensive care units, coronary care units or other facilities where equipment and personnel for constant monitoring of cardiac arrhythmias and blood pressure are available.

Following injection of Bretylium Tosylate there may be a delay of 20 minutes to 2 hours in the onset of antiarrhythmic action, although it appears to act within minutes in ventricular fibrillation. The delay in effect appears to be longer after intramuscular than after intravenous injection.

Bretylium Tosylate Injection, USP Important Safety Information

Contraindications

There are no contraindications to use bretylium tosylate in treatment of ventricular fibrillation or life-threatening refractory ventricular arrhythmias, except in the case of digitalis induced arrhythmias. If the arrhythmia is thought to be due to digitalis, bretylium tosylate should not be used.

Warnings and Precautions

- **Hypotension:** Postural hypotension, subjectively recognized by dizziness, lightheadedness, vertigo or faintness may occur. Some degree of hypotension is present in about 50% of patients while they are supine; patients over 65 years may be at greater risk. Keep patients supine until tolerance to the hypotensive effect of bretylium tosylate develops.
- **Transient Hypertension and Increased Frequency of Arrhythmias:** Transient hypertension or increased frequency of premature ventricular contractions and other arrhythmias may occur in some patients, especially after too vigorous a dosing.
- **Caution During Use with Digitalis Glycosides:** Bretylium tosylate may aggravate digitalis toxicity. In digitalized patients, bretylium tosylate should be used only if the etiology of the arrhythmia does not appear to be digitalis toxicity and other antiarrhythmic drugs are not effective. Avoid simultaneous initiation of therapy with digitalis glycosides and bretylium tosylate.
- **Patients with Fixed Cardiac Output:** Bretylium tosylate should be avoided in patients with fixed cardiac output since severe hypotension may result.
- **Hyperthermia:** Hyperthermia, characterized by temperature excess of 106°F, has been reported.
- **General Precautions:**
 - Bretylium Tosylate Injection, USP should be diluted prior to intravenous use, but may be given undiluted for immediately life-threatening ventricular arrhythmias.
 - When injected intramuscularly, not more than 5 mL should be given in a site, and injection sites should be varied.
 - Dosage intervals should be increased in patients with impaired renal function.

Adverse Reactions

Hypotension and postural hypotension are the most frequently reported adverse reactions. Nausea and vomiting occurred in about three percent of patients. This is not a complete list of side effects and others may occur. Please see the full Prescribing Information for a complete list of adverse reactions.

To report SUSPECTED ADVERSE REACTIONS, contact ANI Pharmaceuticals, Inc. at 1-800-308-6755 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use Bretylium Tosylate Injection, USP safely and effectively. See full Prescribing Information for Bretylium Tosylate Injection, USP.