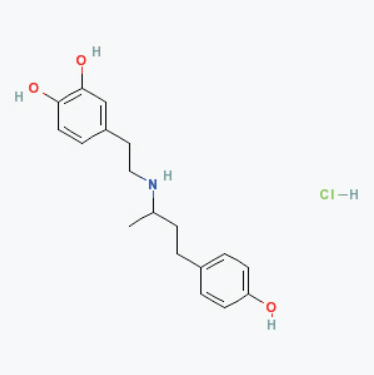
Taj Pharmaceuticals Ltd.

Dobutamine

CAS No. : 49745-95-1

IUPAC Name 4-[2-[4-(4-hydroxyphenyl)butan-2-ylamino]ethyl]benzene-1,2-diol hydroc
hloride



Molecular Structure

CAS Number 49745-95-1
Chemical Formula C18H24ClNO3
Molecular Weight 337.84106 [g/mol]
Molecular Formula C18H24ClNO3

INGREDIENTS

Name (Active Moiety) Type Strength
Dobutamine Hydrochloride (Dobutamine) Active 12.5 MILLIGRAM In 1 MILLILITER
Sodium Metabisulfite Inactive 0.2 MILLIGRAM In 1 MILLILITER
Hydrochloric Acid Inactive
Sodium Hydroxide Inactive

DOSAGE

Do not add dobutamine to 5% Sodium Bicarbonate Injection or to any other strongly alkaline solution. Because of potential physical incompatibilities, it is recommended that dobutamine not be mixed with other drugs in the same solution. Dobutamine should not be used in conjunction with other agents or diluents containing both sodium bisulfite and ethanol.

Preparation and Stability

At the time of administration, dobutamine must be further diluted in an IV container to at least a 50-mL solution using one of the following intravenous solutions as a diluent: 5% Dextrose Injection, 5% Dextrose and 0.45% Sodium Chloride Injection, 5% Dextrose and 0.9% Sodium Chloride Injection, 10% Dextrose Injection, lsolyte® M with 5% Dextrose Injection, Lactated Ringer's Injection, 5% Dextrose in Lactated Ringer's Injection, Normosol® M in D5-W, 20% Osmitrol® in Water for Injection, 0.9% Sodium Chloride Injection, or Sodium Lactate Injection. Intravenous solutions should be used within 24 hours.

Recommended Dosage

Infusion of dobutamine should be started at a low rate (0.5-1.0 µg/kg/min) and titrated at intervals of a few minutes, guided by the patient's response, including systemic blood pressure, urine flow, frequency of ectopic activity, heart rate, and (whenever possible) measurements of cardiac output, central venous pressure, and/or pulmonary capillary wedge pressure. In reported trials, the optimal infusion rates have varied from patient to patient

SIDE EFFECTS

Increased Heart Rate, Blood Pressure, and Ventricular Ectopic Activity- A 10 to 20 mm increase in systolic blood pressure and an increase in heart rate of 5 to 15 beats/minute have been noted in most patients (see WARNINGS regarding exaggerated chronotropic and pressor effects). Approximately 5% of patients have had increased premature ventricular beats during infusions. These effects are dose related.

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Hypotension- Precipitous decreases in blood pressure have occasionally been described in association with Dobutamine therapy. Decreasing the dose or discontinuing the infusion typically results in rapid return of blood pressure to baseline values. In rare cases, however, intervention may be required and reversibility may not be immediate.

Reactions at Sites of Intravenous Infusion- Phlebitis has occasionally been reported. Local inflammatory changes have been described following inadvertent infiltration. Isolated cases of cutaneous necrosis (destruction of skin tissue) have been reported.

Miscellaneous Uncommon Effects- The following adverse effects have been reported in 1% to 3% of patients: nausea, headache, anginal pain, nonspecific chest pain, palpitations, and shortness of breath. Isolated cases of thrombocytopenia have been reported.

Administration of Dobutamine hydrochloride, like other catecholamines, can produce a mild reduction in serum potassium concentration, rarely to hypokalemic levels (see PRECAUTIONS).

Longer-Term Safety- Infusions of up to 72 hours have revealed no adverse effects other than those seen with shorter infusions.

PRECAUTIONS

1. During the administration of Dobutamine Injection, USP, as with any adrenergic agent, ECG and blood pressure should be continuously monitored. In addition, pulmonary wedge pressure and cardiac output should be monitored whenever possible to aid in the safe and effective infusion of Dobutamine hydrochloride.

2. Hypovolemia should be corrected with suitable volume expanders before treatment with Dobutamine hydrochloride is instituted.

No improvement may be observed in the presence of marked mechanical obstruction, such as severe valvular aortic stenosis.

Usage Following Acute Myocardial Infarction- Clinical experience with Dobutamine hydrochloride following myocardial infarction has been insufficient to establish the safety of the drug for this use. There is concern that any agent that increases contractile force and heart rate may increase the size of an infarction by intensifying ischemia, but it is not known whether Dobutamine hydrochloride does so.
Laboratory Tests

Dobutamine, like other β2-agonists, can produce a mild reduction in serum potassium concentration, rarely to hypokalemic levels. Accordingly, consideration should be given to monitoring serum potassium.

INTERACTION

Animal studies indicate that Dobutamine may be ineffective if the patient has recently received a β-blocking drug. In such a case, the peripheral vascular resistance may increase.

Preliminary studies indicate that the concomitant use of Dobutamine and nitroprusside results in a higher cardiac output and, usually, a lower pulmonary wedge pressure than when either drug is used alone.

There was no evidence of drug interactions in clinical studies in which Dobutamine was administered concurrently with other drugs, including digitalis preparations, furosemide, spironolactone, lidocaine, nitroglycerin, isosorbide dinitrate, morphine, atropine, heparin, protamine, potassium chloride, folic acid, and acetaminophen.

DRUG DESCRIPTION

Dobutamine is a sympathomimetic drug used in the treatment of heart failure and cardiogenic shock. Its primary mechanism is direct stimulation of β1 receptors of the sympathetic nervous system.

Dobutamine is a clear, practically colorless, sterile, nonpyrogenic solution of Dobutamine hydrochloride for intravenous use only. Each milliliter contains 12.5 mg (41.5 µmol) Dobutamine, as the hydrochloride and sodium metabisulfite, 0.2 mg added as antioxidant. May contain hydrochloric acid and/or sodium hydroxide for pH adjustment. pH is 3.3 (2.5 to 5.5).Dobutamine Hydrochloride, USP is chemically designated (±)-4-[2-[[3-(ρ-hydroxyphenyl)-1-methylpropyl] amino] ethyl]-pyrocatechol hydrochloride.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to themanufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

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