Only for the use of Medical Professionals

Dobumin®

Dobutamine Hydrochloride

Description

Dobumin¨ injection is a preparation of Dobutamine Hydrochloride. It is a direct-acting inotropic agent whose primary activity results from stimulation of the ß receptors of the heart while producing comparatively mild chronotropic, hypertensive, arrhythmogenic and vasodilative effects. In patients with depressed cardiac function Dobumin¨ increases the cardiac output to a similar degree and the cardiac stroke volume is usually increased. Systemic vascular resistance is usually decreased with administration of Dobutamine Hydrochloride.

Indications

Dobumin¨ injection is indicated when parenteral therapy is necessary for inotropic support in the short-term treatment of patients with cardiac decompensation due to depressed contractility resulting either from organic heart disease or from cardiac surgical procedures.

Dosage and administration

Dobutamine Hydrochloride is a potent drug. It is not for direct injection and must be diluted exactly as directed before administration to patients as an I.V. infusion.

Reconstitution and Stability: At the time of administration, Dobutamine Hydrochloride injection must be further diluted in an I.V. 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; 5% Dextrose in Lactated Ringer's Injection; Sodium Lactate injection. Intravenous solutions should be used within 24 hours.

Adults

Recommended Dosage: The rate of infusion needed to increase cardiac output usually ranged from 2.5 to 15 mcg/kg/min (see table). On rare occasions, infusion rates up to 40mcg/kg/min have been required to obtain the desired effect.

Rates of Infusion for Concentrations of 250, 500, and 1,000 mcg/ml

Drug Delivery Rate (mcg/kg/min)	Infusion Delivery Rate 250 mcg/ml* (ml/kg/min)	500 mcg/ml** (ml/kg/min)	1,000 mcg/ml*** (ml/kg/min)
2.5	0.01	0.005	0.0025
5	0.02	0.01	0.005
7.5	0.03	0.015	0.0075
10	0.04	0.02	0.01
12.5	0.05	0.025	0.0125
15	0.06	0.03	0.015

* 250 mcg/ml of diluent

** 500 mcg/ml or 250 mg/500 ml of diluent

*** 1,000 mcg/ml or 250 mg/250 ml of diluents

Rate of Administration: When administering Dobutamine (or any potent medication) by continuous intravenous infusion, it is advisable to use a precision volume control I.V. set.

The rate of administration and the duration of therapy should be adjusted according to the patient's response as determined by heart rate, presence of ectopic activity, blood pressure, urine flow, and, whenever possible, measurement of central venous or pulmonary wedge pressure and cardiac output.
Concentrations of up to 5,000 mg/l have been administered to humans (250 mg/50 ml). The final volume administered should be determined by the fluid requirements of the patient.

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

Children
This preparation is not intended for use in children.

Use in pregnancy and lactation
Reproduction studies performed in rats and rabbits have revealed no evidence of harm to the fetus due to Dobutamine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dobutamine is administered to a nursing woman. If a mother requires Dobutamine treatment, breastfeeding should be discontinued for the duration of the treatment.

Precautions
During the administration of Dobutamine Hydrochloride injection 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. Hypovolemia should be corrected with suitable volume expanders before treatment with Dobutamine is instituted.

Side effects
The most common adverse reactions are related to the effect of Dobutamine on the cardiovascular system e.g., increased heart rate, blood pressure, and ventricular ectopic activity; these effects were dose-related. About 5% of patients have had increased premature ventricular beats during infusions. An increase in heart rate of 5 to 15 beats/minute and a 10 to 20 mmHg increase in systolic blood pressure have been noted in most patients. There have been reports of precipitous decreases in blood pressure (hypotension) associated with Dobutamine therapy. Less commonly occurring effects relating to the cardiovascular system include cardiac awareness, transient bigeminy, bradycardia, angina, nonspecific chest pain, palpitations, and shortness of breath. Mild side effects are nausea, headache, anginal pain, nonspecific chest pain, palpitations, shortness of breath , decreases in serum potassium concentrations, dyspnea, thrombocytopenia, pruritus, chill, sweating and phlebitis were observed rarely.

Contraindications
Dobutamine Hydrochloride injection is contraindicated in patients with idiopathic hypertrophic subaortic stenosis and in patients who have shown hypersensitivity to Dobutamine.

Warnings
Dobutamine Hydrochloride injection may cause a marked increase in heart rate or blood pressure, especially systolic pressure. Patients with atrial fibrillation are at risk of developing rapid ventricular response. Patients with preexisting hypertension appear to face an increased risk of developing an exaggerated pressor response. In patients who have atrial fibrillation with rapid ventricular response, a digitalis preparation should be used prior to institution of therapy with Dobutamine. Administration of Dobutamine may cause skin rash, fever, eosinophilia, and bronchospasm, have been reported occasionally.

Drug interactions
Clinical 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. No evidence of drug interactions was noted in clinical studies when Dobutamine was administered concurrently with other drugs including furosemide and/or digitalis preparations, spironolactone, lidocaine, isosorbide dinitrate, glyceryl trinitrate, atropine, morphine, anticoagulants and potassium chloride supplements.

Overdose
Overdoses of Dobutamine have been reported rarely. The initial actions to be taken in a Dobutamine Hydrochloride overdose are discontinuing administration, establishing an airway, and ensuring oxygenation and ventilation. Resuscitative measures should be initiated promptly. Severe ventricular tachyarrhythmias may be successfully treated with propranolol or lidocaine. Hypertension usually responds to a reduction in dose or discontinuation of therapy. Absorption of drugs from the gastrointestinal tract may be decreased by giving activated charcoal, which, in many cases, is more effective than emesis or lavage; consider charcoal instead of or in addition to gastric emptying. Repeated doses of charcoal over time may hasten elimination of some drugs that have been absorbed. Safeguard the patient's airway when employing gastric emptying or charcoal. Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been established as beneficial for an overdose of Dobutamine Hydrochloride.

Pharmaceutical precautions
Store in a cool and dry place. Protect from light.☐☐Presentation
Dobumine¨ 20 ml IV injection: A clear, colorless or slightly yellow sterile solution. Each ml contains Dobutamin 12.5 mg as Hydrochloride USP.

Package quantities
Dobumine¨ 20 ml IV injection: Carton of 20ml vial.

® Registered Trade Mark

ACI Limited

Narayanganj, Bangladesh