DOBUTAMINE HYDROCHLORIDE

Dobuzef ®

50 mg/mL (250 mg/5 mL)
Solution for Injection (IV Infusion)
ADRENERGIC AGENT

℞

FORMULATION
Each mL contains:
Dobutamine (as hydrochloride) ..... 50 mg

PRODUCT DESCRIPTION
Colorless to pale yellowish transparent solution in clear colorless glass ampoule.

INDICATION
Dobutamine Hydrochloride Injection is used to increase the contractility of the heart in acute heart failure, as occurs in cardiogenic shock and myocardial infarction; it is also used in septic shock.

PHARMACOKINETICS
Dobutamine is inactive when given orally, and its rapidly inactivated in the body by similar processes. It has a half-life of about 2 minutes. Conjugates of dobutamine and its major metabolites 3-0-methyldobutamine are excreted primarily in urine, with small amounts eliminated in the feces.

DOSAGE AND ADMINISTRATION
Dobutamine is given as the hydrochloride but doses are expressed in terms of the base: 1.12 micrograms of the hydrochloride is approximately equivalent to 1 microgram of base.
It is administered by intravenous infusion as a dilute solution (0.25 to 5 mg/mL) in Glucose 5% or Sodium Chloride 0.9%; other fluids may also be suitable.
In the management of acute heart failure, dobutamine is given at a usual rate of 2.5 to 10 micrograms/kg per minute, according to the patient's heart rate, blood pressure, cardiac output and urine output. A range of 0.5 up to 40 micrograms/kg per minute has occasionally been required. It has been recommended that the treatment with dobutamine should be discontinued gradually.
Dobutamine is also used as alternative to exercise in cardiac stress testing. A solution containing 1 mg/mL is employed for this purpose, given via an infusion pump. A dose is then increased by increments of 5 micrograms/kg per minute, with each dose being infused for 8 minutes before the next incremental increase of doses up to 40 micrograms/kg per minute has sometimes been used. The ECG should be monitored continuously and the infusion terminated if arrhythmias, marked ST segment depression, or other adverse effect occurs. Or as prescribed by the physician.

CONTRAINDICATIONS
Dobutamine hydrochloride is contraindicated in patients with idiopathic hypertrophic subaortic stenosis and in patients who have shown previous manifestations of hypersensitivity to Dobutamine Hydrochloride Injection solution.

ADVERSE REACTION
1. Hypersensitivity: Hypersensitivity reactions have been reported in patients receiving dobutamine infusions, possibly due to sodium sulfite in the formulation. Redness, swelling, itching and sensation of warmth developed around the infusion site in a patient receiving dobutamine; the reactions recurred when the infusion was repeated a week later. Eosinophilic reactions have also been reported, including hypersensitivity myocarditis and asthma.
2. Effects on the cardiovascular system: For reference to severe cardiovascular complications of dobutamine stress echocardiography.
3. Effects on the neuromuscular sytem: Myoclonus has been reported in patients with renal impairment given dobutamine infusion for heart failure.
4. Effects on the skin: Troublesome pruritus of the scalp has been reported in patients receiving dobutamine infusions. It was suggested that this might be direct effect of dobutamine since the reaction was so localized.

PRECAUTIONS
1. Dobutamine is incompatible with alkaline solutions such as Sodium Bicarbonate or any alkaline solution. Diluted solutions must be used within 24 hours.
2. Dobutamine has primarily inotropic effects and should be avoided or used only with great caution in patients with marked obstruction of cardiac ejection, such as idiopathic hypertrophic subaortic stenosis. It should also be used with caution in patients with acute myocardial infarction, and in cardiogenic shock complicated by severe hypotension.
3. Hypovolemia should be corrected before treatment.

DRUG INTERACTION
Most interactions with dobutamine are due to its direct $beta_1$ agonist effects on the heart but use with beta blockers may allow its alpha- and $beta_2$ -agonist effects to become apparent.

PREGNANCY AND LACTATION
1. Reproduction studies performed in rats and rabbits have revealed no evidence of harm to the fetus due to dobutamine. However, the drugs has not been administered to pregnant women and should be used only when expected benefits clearly outweigh the potential risks to the fetus.
2. It is not known whether dobutamine crosses the placenta or is excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when dobutamine hydrochloride is administered to nursing women. If a mother requires treatment with dobutamine hydrochloride, breastfeeding should be discontinued for the duration of treatment.

PEDIATRIC
Safety and effectiveness in children have not been established. Therefore, this drug should not be administered to the pediatrics.

GERIATRIC
Caution should be exercised in treating the elderly patients, who are more likely to be suffering from adverse reactions, with the lowest effective dose.

OVERDOSAGE
A patient received an accidental overdose of dobutamine when given an intravenous infusion at a rate of more than 130 micrograms/kg per minute for 30 minutes, this being three times the recommended maximum. Characteristic adverse effects such as emesis, palpitations, chest pain, dyspnea, and paraesthesia developed, together with urinary incontinence, an effect not previously associated with dobutamine.

CAUTION
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
USP Type 1 Glass Ampoule x 5 mL (Box of 10's)

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