

SIZE L 90 x H 170MM

For doses in children, see below.

#### ACTION

Although dobutamine is usually considered to be a beta agonist, animal studies suggest that its ability to stimulate alpha- and beta-adrenergic receptors may be as great as its beta-stimulant properties. It has been proposed that the inotropic action results from a combination of alpha-stimulant activity on myocardial alpha1 receptors, a property residing mainly in the (-) -enantiomer, with beta stimulation by the (+)-enantiomer; peripherally, alpha-mediated vasoconstriction would be opposed by the beta-agonist properties of the (+) -enantiomer, resulting in the net inotropic action with relatively little effect on blood pressure seen with the racemic mixture used clinically

Dobutamine has a thermogenic effect, increasing oxygen delivery and utilisation in healthy individuals.

However, using it for this purpose in critically ill patients did not improve patient outcome and in some cases might have been harmful.

#### ADMINISTRATION IN CHILDREN.

Dobutamine and dopamine are both used for inotropic support in children. A study in children undergoing cardiac surgery suggested that dobutamine may be preferred to dopamine since the latter could cause pulmonary vasoconstriction (see under Precautions for Dopamine). In preterm infants, low systemic blood flow is associated with cerebral haemorrhage and neurodevelopmental disability, and both dobutamine and dopamine have been studied for their effects on outcomes. Of the two drugs, dopamine produces the greater reduction in hypotension, but dobutamine increases superior vena cava flow to a greater extent. Although it has been argued that superior vena cava flow, rather than blood pressure, provides a more meaningful indication of systemic blood flow in neonates, in reality the difference may not be clinically important: while low superior vena cava flow was associated with neurodevelopmental delays at 3 years of age, there was no significant difference in combined death and disability rates between infants given dobutamine or dopamine to correct it. Neonates, infants, and children may be given dobutamine by continuous intravenous infusion for inotropic support in an initial dose of 5 micrograms/kg per minute, adjusted according to response to between 2 and 20 micrograms/kg per minute.

#### ADVERSE EFFECTS AND TREATMENT

As for Sympathomimetics. Dobutamine has mainly beta-agonist properties and its principal adverse effects include dose-related increases in heart rate and blood pressure, ectopic beats, angina or chest pain, and palpitations; dosage should be reduced or temporarily stopped if they occur. Ventricular tachycardia may occur rarely; cardiac rupture has been reported rarely during dobutamine stress testing.

#### OVERDOSE

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, dyspnoea, and paraesthesia developed, together with urinary incontinence, an effect not previously associated with dobutamine.

#### PRECAUTIONS

As for Sympathomimetics. Dobutamine has 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. Hypovolaemia should be corrected before treatment.

#### INTERACTIONS

As for Sympathomimetics. Most interactions with dobutamine are due to its direct beta agonist effects on the heart, but use with beta blockers may allow its alpha- and beta-agonist effects to become apparent.

**Storage:** - Store at controlled room temperature 15°C to 30°C. Protect from light. Do not allow to freeze.

**Improper Storage may Deteriorate the product**

**Keep the medicine out of reach of children.**

**Presentation:** -Each pack contain 5 ampoules of 5 ml tray pack in a cartons

Manufactured by:

**AMERICAN REMEDIES®**  
Care & Cure with Research  
American Remedies Healthcare Pvt. Ltd.  
(An ISO 9001:2015 Certified Company)  
ICO: American Remedies LLC, DE, USA

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SIZE L 90 x H 170MM

For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

## R<sub>x</sub> Dobutamine Injection I.P.

AMERICAN

**DOBUTACAN**

Must be diluted Prior to use.

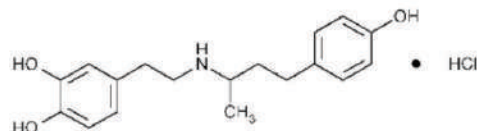
#### Composition:-

Each ml Contains:-

|                          |      |       |
|--------------------------|------|-------|
| Dobutamine Hydrochloride | I.P. | 50 mg |
| Eq. to Dobutamine        |      |       |
| Water for Injection      | I.P. | q.s.  |

#### Description:-

Dobutamine is a β<sub>1</sub>-adrenergic agonist that also displays weak agonist activity at β<sub>2</sub>- and α<sub>1</sub>-adrenergic receptors. Dobutamine is a positive inotrope, stimulating sympathetic nervous system activity to increase cardiac output. Dobutamine is clinically used to treat heart failure and cardiogenic shock and is used in research models to induce cardiac dysfunction. Dobutamine also decreases GABAergic, glycinergic, and glutamatergic neurotransmission to cardiac vagal neurons. The structural formula of dobutamine Hydrochloride is as.



Dobutamine Hydrochloride

#### PHARMACOLOGY

##### Pharmacokinetics

Like adrenaline, dobutamine is inactive when given orally. And it is rapidly inactivated in the body by similar processes. It has a half-life of about 2 minutes. Conjugates of dobutamine and its major metabolite 3-O- methylldobutamine are excreted mainly in urine, with small amounts eliminated in the faeces.

The main mechanism of clearance of dobutamine appears to be distribution to other tissues, and not metabolism or elimination. It has a half-life of about 2 minutes and plasma concentrations of dobutamine reach steady state about 10 to 12 minutes after the start of an infusion. Dobutamine is used mainly for the short-term treatment of heart failure and any pharmacokinetic changes in this condition have no clinical implications in dosage Titration.

The pharmacokinetics of dobutamine and other cardiovascular drugs in children have been reviewed.

#### DOSAGE AND ADMINISTRATION

Dobutamine is a sympathomimetic with direct effects on beta-adrenergic receptors, giving it a prominent inotropic action on the heart. It also has some alpha- and beta-agonist properties. Although it is structurally related to dopamine, it has no specific dopaminergic properties; however, like dopamine, the inotropic action of dobutamine on the heart is associated with less cardiac accelerating effect than that of isoprenaline.

Dobutamine 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. Other circumstances in which its inotropic action may be useful are during cardiac surgery and positive end-expiratory pressure ventilation.

Dobutamine is used as the hydrochloride but doses are expressed in terms of the base; 1.12 micrograms of the hydrochloride is equivalent to about 1 microgram of base. It is given 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 and the manufacturers' guidelines should be consulted.

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 treatment with dobutamine should be stopped gradually.

Dobutamine is also used as an alternative to exercise in cardiac stress testing. A solution containing 1 mg/ml is given via an infusion pump in a dose of 5 micrograms/kg per minute for 8 minutes. The dose is then increased by increments of 5 micrograms/kg per minute up to a usual maximum of 20 micrograms/kg per minute, with each dose being infused for 8 minutes before the next increase; doses of up to 40 micrograms/kg per minute have sometimes been used. The ECG should be monitored continuously and the infusion stopped if arrhythmias, marked ST segment depression, or other adverse effects occur.