Only for the use of Professionals

Cardopa®

Dopamine hydrochloride

Description

Cardopa® is a preparation of Dopamine hydrochloride which can stimulate α, β and dopamine receptors. It is a natural catecholamine formed by the decarboxylation of 3,4-dihydroxyphenylalanine (DOPA). Dopamine is a precursor to norepinephrine in noradrenergic nerves and is also a neurotransmitter in certain areas of the central nervous system, especially in the nigrostriatal tract and in a few peripheral sympathetic nerves. It produces positive chronotropic and inotropic effects on the myocardium, resulting in increased heart rate and cardiac contractility. This is accomplished directly by exerting an agonist action on β-adrenoceptors and indirectly by causing release of norepinephrine from storage sites in sympathetic nerve endings. Dopamine does not cross the blood-brain barrier and so does not activate dopamine receptors in the brain.

Indications

Cardopa® is indicated for the correction of hemodynamic imbalances present in:

- Acute hypotension or shock associated with myocardial infarction, endotoxic septicaemia, trauma and renal failure
- As an adjunct after open heart surgery, where there is persistent hypotension after correction of hypovolaemia
- In chronic cardiac decompensation as in congestive failure

Dosage and administration

Adult dose:

Where appropriate, the circulating blood volume must be restored with a suitable plasma expander or whole blood, prior to administration of dopamine. Begin infusion of dopamine hydrochloride solution at dosage of 2 to 5 micrograms/kg/min in patients who are likely to respond to modest increment of heart force and renal perfusion.

In more seriously ill patients, begin infusion of dopamine hydrochloride solution at dosage of 5 micrograms/kg/min and increase gradually using 5 to 10 micrograms/kg/min increment up to 20 to 50 micrograms/kg/min as needed. If dosage in excess of 50 micrograms/kg/min are required, it is

suggested that urine output should be checked frequently. In patients who do not respond to this doses, additional increments of dopamine may be given in an effort to achieve adequent blood pressure, urine flow and perfusion.

For patients with severe, refractory, chronic congestive heart failure doses should be started on 0.5 to 2 micrograms/kg/min, and the dose increased by 1 to 3 micrograms/kg/min as urinary output increases.

Note: *ECG, blood pressure and urine output should be monitored. Cardiac output and pulmonary wedge pressure should be monitored if possible.*

Children less than 12 years old: The safety and efficacy of dopamine in children under 12 years has not been established.

Geriatric patients: No variation in dosage is suggested for geriatric patients. However, close monitoring is required for blood pressure, urine flow, and peripheral tissue perfusion.

Dilution technique: Dopamine hydrochloride must be diluted before administration to patients. Transfer contents of one or more ampoules by aseptic technique to either 250 ml or 500 ml of one of the following sterile intravenous solutions: 0.9% Sodium Chloride, 5% Dextrose, 5% Dextrose and 0.9% Sodium Chloride, 5% Dextrose in 0.45% Sodium Chloride, 5% Dextrose in Ringer's Lactate, Sodium Lactate (1/6 Molar), Ringer's Lactate. Dopamine hydrochloride has been found to be stable for a minimum of 24 hours after dilution in the sterile intravenous solutions listed above. However, as with all intravenous admixtures, dilution should be made just prior to administration. Do not add dopamine hydrochloride solution to sodium bicarbonate or other alkaline intravenous solutions, since the drug is inactivated in alkaline solution. Mixing of dopamine hydrochloride with alteplase in the same container should be avoided as visible particulate matter has been observed. It is recommended that dopamine should not be added to amphotericin B solution because amphotericin B is physically unstable in dopamine-containing solutions.

Rate of administration: After dilution dopamine hydrochloride is administered intravenously through a suitable intravenous catheter or needle. An intravenous drip chamber or other suitable metering device is essential for controlling the rate of flow in drops per minute. Each patient must be individually titrated to the desired haemodynamic and/or renal response with dopamine hydrochloride. In titrating to the desired increase in systolic blood pressure, the optimum dosage rate for renal response may be exceeded, thus necessitating a reduction in rate after the haemodynamic condition is stabilized. Administration rate greater than 50 micrograms/kg/minute

have safely been used in advanced circulatory decompensation states. If unnecessary fluid expansion is of concern, adjustment of drug concentration may be preferred over increasing the flow rate of a less concentrated dilution.

Use in pregnancy and lactation

Animal studies have revealed no evidence of teratogenic effects from dopamine hydrochloride. The drug may be used in pregnant women when in the judgment of the physician the expected benefits outweigh the potential for risk to the fetus. It is not known if dopamine hydrochloride is excreted in breast milk, nor is the effect on the infant known. It is not recommended for breast-feeding mothers unless the expected benefits outweigh any potential risks

Warnings

Dopamine hydrochloride should not be administered in the presence of uncorrected tachyarrhythmia or ventricular fibrillation. It is metabolized in the tissues and blood by monoamine oxidase (MAO) and catechol-O-methyltransferase (COMT). Dopamine hydrochloride and its metabolites are almost completely excreted in the urine. Patients who have been treated with monoamine oxidase inhibitors (MAOI) prior to the administration of dopamine will require substantially reduced dosages of later. The starting dose in such patients should be reduced to at least one-tenth (1/10) of the usual dose. Excess administration of potassium-free solutions may result in significant hypokalemia. The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentration, overhydration, congested states or pulmonary oedema. Closely monitoring is advised in patients with impaired renal and hepatic function.

Precautions

Hypovolaemia should be corrected where necessary prior to treatment with dopamine hydrochloride. If a disproportionate rise in diastolic blood pressure (i.e. a marked decrease in pulse pressure) is observed, the infusion rate should be decreased and the patients observed carefully for further evidence of predominant vasoconstriction activity, unless such effect is desired. Dopamine hydrochloride infusion should be withdrawn gradually, to avoid unnecessary hypotension. Patients with a history of peripheral vascular disease (e.g. atherosclerosis, arterial embolism, Raynaud's disease, cold injury, diabetic endarteritis and Buerger's disease) should be closely monitored for any changes in color or temperature of the skin in the extremities. If ischemia occurs and is thought to be the result of vasoconstriction, the benefits of continued dopamine hydrochloride infusion should be weighed against the risk of possible necrosis. These changes may be reversed by either decreasing the rate or discontinuing the infusion. Dopamine hydrochloride in 5% dextrose solution should be infused into a large vein whenever possible to prevent the possibility of infiltration of perivascular tissue adjacent to the infusion site. Extravasations may cause necrosis and sloughing of the surrounding tissue. Ischaemia can be reversed by infiltration of the affected area with 10-15ml

of saline containing 5 to 10mg Phentolamine mesylate. Dopamine hydrochloride should be used with extreme caution in patients inhaling cyclopropane or halogenated hydrocarbon anaesthetics due to the arterial arrhythmogenic potential. Dextrose solutions should be used with caution in patients with known subclinical or over diabetes mellitus.

Side effects

The most frequent reported adverse reactions are ectopic beats, nausea, vomiting, tachycardia, anginal pain, palpitations, dyspnoea, headache, hypotension, hypertension and vasoconstriction. Other less frequent adverse reactions are aberrant ventricular conduction, bradycardia, piloerection, mydriasis, widened QRS complex, azotaemia and elevated blood pressure. Peripheral ischemic gangrene in patients with pre-existing vascular disease. Fatal ventricular arrhythmias have been reported on rare occasions.

Contraindications

Dopamine hydrochloride is contraindicated in patients with known hypersensitivity to dopamine or any of its ingredients. It should not be used in patients with phaeochromocytoma, uncorrected tachyarrhythmias, or ventricular fibrillation. Dextrose solution without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination of red cells.

Drug interactions

The action of dopamine hydrochloride is potentiated by monoamine oxidase inhibitors (MAOI's). The concurrent administration of cyclopropane or halogenated hydrocarbon anesthetics may cause ventricular arrhythmias. The cardiac effects of dopamine hydrochloride are antagonized by β - adrenergic blocking agents such as Propranolol and Metoprolol. The ergot alkaloids should be avoided because of the possibility of excessive vasoconstriction. Tricyclic antidepressants and guanethidine may potentiate the pressor response to dopamine hydrochloride. Hypotension and bradycardia have been observed in patients receiving Phenytoin. Dopamine hydrochloride may increase the effect of diuretic agents. Peripheral vasoconstriction may be antagonized by α - adrenergic blocking agents, such as Phentolamine. Other vasodilators may also be useful in patients with heart failure, allowing greater inotropic and renal effects without the associated vasoconstriction. Care must be taken to avoid hypotension.

Overdose

In case of accidental overdosage, as evidenced by excessive blood pressure elevation, reduce the

rate of administration or temporarily discontinue dopamine hydrochloride until the patients condition stabilized. Since the duration of action of dopamine hydrochloride is quite short, no additional measures are usually necessary. If these measures fail to stabilize the patient's condition, use of the short-acting α -adrenergic blocking agent such as Phentolamine should be considered.

Pharmaceutical precautions

Store below 25°C. Protect from light.

Presentation

Cardopa® I.V. Injection: Each 5ml sterile solution contains Dopamine HCl BP 200mg.

Package quantities

Cardopa® I.V. Injection: Cartons of 5X5 ml ampoule.

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