

DOPAMINE HYDROCHLORIDE INJECTION USP

200mg / 5 ml

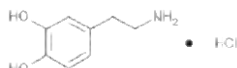
COMPOSITION :

Each ml contains:
Dopamine Hydrochloride USP 40 mg
Water for Injection USP q.s.

CATEGORY :

Cardiac stimulants

Prescription only medicine



Molecular Formula : $C_8H_{11}NO_2 \cdot HCl$
Molecular weight : 189.64

PHARMACOLOGICAL ACTION :

Dopamine Hydrochloride exerts a positive inotropic effect on the myocardium, acting as an agonist at beta1-adrenergic receptors. In addition, it has the capacity to release norepinephrine from nerve terminals, and this also contributes to its effects on the heart. Dopamine Hydrochloride appears to increase systolic and pulse pressure and has either no effect on or slightly increases diastolic blood pressure. Total peripheral resistance is usually unchanged when low or intermediate therapeutic doses are given. This is probably due to the ability of Dopamine Hydrochloride to reduce regional arterial resistance in the mesentery and the kidney, while producing minor increases in other vascular beds. The effect of Dopamine Hydrochloride on the renal vasculature appears to be mediated by a specific dopaminergic receptor. In relatively low doses, infusion of 2 µg/kg/minute. Dopamine Hydrochloride is associated with an increase in glomerular filtration rate, renal blood flow, and sodium excretion (dopaminergic mechanism.)

INDICATIONS:

Dopamine Hydrochloride is used in the treatment of:

Shock unresponsive to replacement of fluid loss and especially where renal function is impaired.

To correct haemodynamic imbalances associated with myocardial infarction, trauma, septic shock, and cardiac surgery.

It is also used in the management of chronic refractory congestive heart failure.

CONTRA-INDICATIONS:

Dopamine Hydrochloride should not be used in patients suffering from pheochromocytoma or in the presence of uncorrected tachyarrhythmias or ventricular fibrillation.

WARNINGS:

Abrupt discontinuation of the infusion can lead to vascular collapse.

Extreme caution must be exercised when using Dopamine Hydrochloride together with anaesthetics like cyclopropane, halothane and other halogenated anaesthetics. Patients who have been treated with monoamine oxidase (MAO) inhibitors prior to the administration of Dopamine Hydrochloride will require substantially reduced dosages.

Dopamine Hydrochloride is metabolised by MAO, and inhibition of this enzyme prolongs and potentiates the effect of Dopamine Hydrochloride. The starting dose in such patients should be reduced to at least one-tenth of the usual dose.

DOSAGE AND DIRECTIONS FOR USE:

Do not use the intravenous infusion if it is darker than slightly yellow or discoloured in any other way. For intravenous infusion only.

Do not add Dopamine Hydrochloride to 5% Sodium bicarbonate or any alkaline intravenous solution, since alkalinity inactivates dopamine hydrochloride.

Dopamine Hydrochloride MUST be diluted before administration to patient. Dilution should be made just prior to administration.

Suggested Dilution:

To deliver a concentration of 200 µg/mL dopamine hydrochloride:

One ampoule of Dopamine Hydrochloride for Infusion 200 mg/5 mL dissolved in 1 litre of a suitable diluent – or One ampoule of Dopamine Hydrochloride for Infusion 50 mg/10 mL, dissolved in 250 mL of suitable diluent. Suitable diluents may contain sodium chloride and/or dextrose.

Rate of administration:

The initial rate is 2 to 5 µg per kg body mass per minute, gradually increased by 5 to 10 µg per kg per minute according to the patient's blood pressure, cardiac output, and urine output. Up to 20 to 50 µg per kg per minute may be required in seriously ill patients. A reduction in urine flow, without hypotension, may indicate a need to reduce the dose. To avoid tissue necrosis Dopamine Hydrochloride is best administered into a large lumen vein. Large veins of the antecubital fossa are preferred to veins in the dorsum of the hand or ankle. Less suitable infusion sites should be used only if the patient's condition requires immediate attention. More suitable sites should be used as rapidly as possible.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Central effects of Dopamine Hydrochloride include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness, and psychotic states, appetite reduction, nausea, vomiting. Cardiovascular effects are complex: stimulation of the alpha-adrenergic receptors produces vasoconstriction, sometimes sufficiently severe to cause gangrene when infiltrated into the digits, with resultant hypertension; the rise in blood pressure may produce cerebral haemorrhage and pulmonary oedema; reflex bradycardia, but stimulation of beta1 adrenergic receptors of the heart produce tachycardia, cardiac arrhythmias, anginal pain, palpitations, and cardiac arrest; hypotension with dizziness and fainting, and flushing, difficulty in micturition, urinary retention, dyspnoea, altered metabolism, sweating, hypersalivation and headache. Raised blood urea has been reported.

Extravasation of Dopamine Hydrochloride may result in tissue necrosis and sloughing. Angina may be precipitated in patients with angina pectoris. Administer with care to patients with diabetes mellitus or closed angle glaucoma.

The infusion site should be continuously monitored for free flow. Close monitoring of the following parameters - urine flow, cardiac output and blood pressure - during Dopamine Hydrochloride infusion is necessary. It is recommended that on gradual discontinuation of Dopamine Hydrochloride care should be taken to avoid undue hypotension associated with very low dosage levels where vasodilation could predominate.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "Side-effects and special precautions."

In case of accidental overdosage, as evidenced by excessive blood pressure elevation, reduce rate of administration or temporarily discontinue Dopamine Hydrochloride until patient's condition stabilises. Further treatment is symptomatic and supportive.

Management of peripheral ischemia:

To prevent sloughing and necrosis in ischemic areas, the area should be infiltrated as soon as possible with 10 to 15 mL of Saline Solution containing from 5 to 10 mg of Phentolamine (alpha-adrenoreceptor blocker).

A syringe with a fine hypodermic needle should be used, and the solution liberally infiltrated throughout the ischemic areas. Sympathetic blockade with Phentolamine causes local hyperemic changes if the area is infiltrated within 12 hours.

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PRESENTATION :

5 ampoules of 5ml in a plastic tray and each tray packed in a printed carton.

STORAGE :

Store below 25°C. Protect from light. Keep out of the reach of children.

Manufactured in India:

