170x230

Rx Dopamine Hydrochloride Injection IP 200 mg/5ml

DOPADONE™-200

For IV Infusion use only
After Dilution

Composition :
Each ml contains :

Dopamine Hydrochloride IP	40 mg
Water for Injections IP	q.s.

PHARMACOLOGICAL ACTION
Dopamine hydrochloride exerts a positive inotropic effect on the myocardium, acting as an agonist at ß1 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 □g/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: 1. Shock unresponsive to replacement of fluid loss and especially where renal function is impaired.
2. To correct haemodynamic imbalances associated with
myocardial infarction, trauma, septic shock, and cardiac surgery.
3. It is also used in the management of chronic refractory
congestive heart failure.

CONTRA-INDICATIONS
The safety of dopamine hydrochloride in pregnancy and lactation has not been established. The safety and efficacy of dopamine hydrochloride in children has not been established. Dopamine hydrochloride should not be given to patients receiving monoamine oxidase (MAO) inhibitors or within 14 days of discontinuing such treatment. 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 (see "Interactions" below).

DOSAGE AND DIRECTIONS FOR USE
Hypovolaemia should be fully corrected, if possible, before dopamine hydrochloride is used.
Do not use the 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 the patient. Dilution should be made just prior to administration. Dopamine hydrochloride is stable for at least 24 hours after dilution in saline or dextrose.

Suggested Dilution
To deliver a concentration of 200 mg/5 ml dopamine hydrochloride: One ampoule of 200 mg/5 ml dissolved in 1 litre of a suitable diluent.
Suitable diluents may contain sodium chloride and/or dextrose. Rate of Administration
Dopamine hydrochloride should be given via an infusion pump or another suitable metering device to control the rate of flow in drops per minute.
The initial rate is 2 to 5 g per kg body mass per minute, gradually increased by 5 to 10 g per kg per minute according to the patient's blood pressure, cardiac output and urine output. Up to 20 to 50 g 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 ß1 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, piloerection 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.
Great care is also needed in patients with cardiovascular disease such as is chaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension or aneurysms. 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.
Interactions
Dopamine hydrochloride should be used with extreme caution and reduced dosage in patients receiving hydrocarbon anaesthetics as there is an increased risk of severe ventricular arrhythmias. Tricyclic antidepressant agents may potentiate the cardiovascular effects of dopamine hydrochloride. Beta adrenergic blocking agents (e.g. propranolol) antagonise the cardiac effects of dopamine hydrochloride.
MAOI's (or for 3 weeks after withdrawal) prolong and intensify the effects of dopamine hydrochloride. See "CONTRA-INDICATIONS". If concurrent use of dopamine hydrochloride and digitalis glycosides is necessary there may be an increased risk of cardiac arrhythmias. Dopamine hydrochloride and ergot derivatives used concurrently may result in severe hypertension. The use of ergotamine with dopamine hydrochloride may produce peripheral vascular ischaemia and potentiate the possibility of gangrene. Administration of IV phenytoin to patients receiving dopamine hydrochloride may result in bradycardia and hypotension; administer with care.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT
In case of accidental over dosage, 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 Is chaemia To prevent sloughing and necrosis in ischaemic 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 is chaemic areas. Sympathetic blockade with phentolamine causes local hyperaemic changes if the area is infiltrated within 12 hours.

IDENTIFICATION
Clear colourless to slightly yellow solution in clear 5 ml ampoules.

STORAGE INSTRUCTIONS
Store in a cool & dry place, below 25°C.

Keep the medicine out of reach of children.

Presentation : 5 Ampoules of 5 ml each with Leaflet.

Manufactured by :
Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road,
Kala Amb, Distt Sirmaur (H.P.)

Marketed by:
windlas
Windlas Biotech Limited
(A WHO GMP Certified Company)
40/1, Mohabewala Industrial Area,
Dehradun-248110, Uttarakhand
TM: Trademark under registration