INSTRUCTIONS FOR USE — READ CAREFULLY!

FRESENIUS AG
D-61343 Bad Homburg v.d.H., Fed. Republic of Germany

Dopamine Fresenius 200 mg/5 ml

Infusion concentrate

For treatment in conditions of shock

Composition

1 ml contains:

Active constituents:

Dopamine hydrochloride	40 mg
Sodium disulphite (maximum: 2.02 mg SO_2/ml)	3 mg

Other constituents:

Hydrochloric acid
Sodium hydroxide
Water for injections

Indications

Dopamine Fresenius 200 mg/5 ml is indicated for the correction of haemodynamic imbalance present in shock due to cardial infarction, trauma, sepsis, open cardiac surgery, renal failure, and chronic cardiac decompensation (e. g. refractory decompensated cardiac insufficiency); the circulating blood volume should be restored prior to administration in shock due to loss of fluid (hypovolaemic shock).

Contraindications

Adrenal tumour (pheochromocytoma),
Hyperthyroidism (thyrotoxicosis),
Narrow-angle glaucoma,
Hypertrophy of the prostate (prostatic adenoma),
Cardiac dysrhythmia (tachyarrhythmia),
Ventricular fibrillation
Anaesthesia with cyclopropane, halothane, or halogenated anaesthetics,

Dopamine should be used with caution in patients with occlusive vascular disease.
In pregnancy Dopamine should be administered first after special consideration.

Warning

Dopamine Fresenius 200 mg/5 ml should not be administered in patients with bronchial asthma with hypersensitivity to sulphites.

Side-effects

In rare cases nausea, headache, vomiting, goose-flesh (cutis anserina), restlessness, anginal pain, heart consciousness, arrhythmia, tachycardia, hypertension, hypotension and dispnoeas can occur.
With increasing dosage, excessive β-adrenergic stimulation may trigger cardiac arrhythmias (sinus tachycardia, supraventricular and ventricular ectopia), and an increase in left ventricular enddiastolic pressure.
Following high dosage and in the presence of circulatory disturbance in the extremities, there is the risk of tissue and skin necrosis. If inadvertent paravenous infusion occur, there is a risk of paravenous necrosis. Dopamine Fresenius 200 mg/5 ml should therefore be administered using infusion systems (vein catheter).

Counter-measures:
Prompt local infiltration of phentolamine (5—10 mg in 0.9% saline solution).

Note

Sodium disulphite may cause hypersensitivity reactions in some patients, particularly asthmatics. Symptoms of allergic reactions are vomiting, diarrhoea, gasping, acute asthmatic attacks, loss of consciousness or anaphylactic shock.

Interactions

Interactions between Dopamine Fresenius 200 mg/5 ml and the following are possible:

a) solutions of alkalines
(e.g. 5% bicarbonate solution)
(inactivation of dopamine)

b) monoamine oxidase (MAO) inhibitors
(potentiation of dopamine activity; in patients treated with MAO-inhibitors, the initial dose should be reduced to 1/10 of the normal)

c) diuretic agents
(risk of potentiation of effects)

d) tricyclic antidepressants
(risk of cardiac arrhythmia)

e) cyclopropane, halothane, or other halogenated anaesthetics
(risk of cardiac arrhythmia)

f) phenytoin
(risk of hypotentsion)

g) ergot alkaloids
(may increase peripheral vasoconstriction; risk of gangrene)

h) guanethidine
(risk of potentiation of sympathicomimetic effects)

Precautions

Sodium disulphite is a strong reducing agent. It should be taken into consideration that any thiamin (vitamin B_1) will be reduced, if administered simultaneously.

Dosage and Application

Dopamine Fresenius 200 mg/5ml is intended for intravenous infusion after dilution. The infusion solution with Dopamine Fresenius 200 mg/5 ml may be administered using infusion systems.

Caution! Dopamine Fresenius 200 mg/5 ml must never be supplied directly in concentrated form but has to be diluted before administration!

Recommended dilution in one of the following infusion solutions:

1. 0.9% sodium chloride infusion solution
2. 5% glucose infusion solution
3. 5% glucose with 0.9% sodium chloride
4. 5% glucose with 0.45% sodium chloride
5. 5% glucose in lactated Ringer's solution
6. sodium lactate (1/6 molar) solution
7. lactated Ringer's solution

If 1 ampoule of Dopamine Fresenius 200 mg/5 ml is aseptically transferred to one of the recommended infusion solutions, either 500 ml or 250 ml, each ml of these solutions contains 396 µg dopamine hydrochloride or 784 µg dopamine hydrochloride respectively.

After dilution in the above sterile solutions Dopamine Fresenius 200 mg/5 ml is stable for at least 24 hours. However, it is advisable to follow standard practice and dilute immediately prior to use.

Do not use solutions which are discoloured or turbid after addition of Dopamin Fresenius 200 mg/5 ml.

Do not administer Dopamine Fresenius 200 mg/5 ml undiluted as a bolus injection!

After adjustement of blood volume prior to therapy with Dopamine Fresenius 200 mg/5 ml the dosage of Dopamine Fresenius 200 mg/5 ml should be individually adjusted for each patient to ensure optimal improvements in cardiac output and perfusion of vital organs. The dosage should be gradually increased until the required haemodynamic and renal effects are achieved. To avoid the risk of aspiration, ensure that the respiratory tract of somnolent patients is free.

If not otherwise prescribed, the following dosage schedule is recommended:

a) **Low dose**
200 µg/minute
≙ 3 µg/kg body weight/minute

b) **Medium dose**
400—600 µg/minute
≙ 6— 9 µg/kg body weight/minute

b) **High dose**
800—1200 µg/minute
≙ 12— 18 µg/kg body weight/minute

In all cases, it is advisable to start dopamine therapy with a low initial dose, and gradually increment the dose in accordance with individual patient response (circulatory and renal effects). If higher doses (> 20 µg/kg body weight/minute) or maximum doses are required, additional therapy with other catecholamines should be considered. The dosage of Dopamine Fresenius 200 mg/5 ml should be adjusted in accordance with the therapeutic objectives and the patient response. In cases of diminution of urine excretion, increasing tachycardia, or development of arrhythmia, the dosage should be reduced, or therapy with Dopamine Fresenius 200 mg/5 ml temporarily interrupted.
The infusion rate should be monitored carefully to avoid overdosage.
Infusion of Dopamine Fresenius 200 mg/5 ml should not be interrupted abruptly following successful therapy, the dose should be gradually reduced.

Recommended dosage in children:
5—7 µg/kg body weight/minute; increase to 10 µg/kg body weight if necessary.

Note

Dopamine Fresenius 200 mg/5 ml must not be added to alkaline solutions which inactivate dopamine hydrochloride.

Duration of Application

Dopamine Fresenius 200 mg/5 ml should be administered until the hypoperfusion status of the patient has been normalised; this may be hours or days. In single cases the duration of application may be continue until 4 weeks.

Do not use Dopamine Fresenius 200 mg/5 ml after expiry date!

Do not use if the solution is cloudy or if the container is damaged.

Store protected from light and not above 25 °C!

Keep out of the reach of children!

Presentation

10 x 5 ml ampoules

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