

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sterile Dopamine Concentrate BP 160mg/ml, 5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of sterile concentrate contains 160mg Dopamine hydrochloride

Each 5ml ampoule contains 800 mg of Dopamine Hydrochloride

Excipients: Each ml of sterile concentrate contains 2.42mg of sodium and 10.0mg sodium metabisulphite (E223)

Each 5ml ampoule contains 12.1mg sodium and 50mg sodium metabisulphite (E223)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.

Clear, colourless or pale yellow sterile concentrate for solution for infusion.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the correction of haemodynamic imbalance such as is seen in circulatory decompensation accompanying myocardial infarction, trauma, endotoxic septicaemia, renal failure, congestive cardiac failure and open heart surgery.

4.2 Posology and method of administration

For intravenous administration by infusion only, after dilution, into medium to large size veins.

Adults including the elderly:

The initial rate of infusion is 2 to 5 micrograms per kilogram body weight per minute and this may be increased gradually by increments of 5 to 10 micrograms/kg/minute until the optimum dose for the individual is achieved.

Up to 50 micrograms/kg/minute may be required and even higher doses have been used.

The usual dilution is 1,600 micrograms per ml and this may be achieved by transfer, aseptically, of 800mg of dopamine hydrochloride to 500ml of one of the following sterile intravenous solutions:-

Sodium Chloride Injection

5% Dextrose Injection

5% Dextrose and 0.9% Sodium Chloride Injection

5% Dextrose and 0.45% Sodium Chloride Solution

5% Dextrose in Ringer Lactate Solution

Sodium Lactate 1/6 Molar Injection

Lactated Ringer's Injection

Alkaline solutions such as 5% sodium bicarbonate should NOT be added to dopamine hydrochloride because the drug will be inactivated.

Children:

Safety and effectiveness in children have not been established.

4.3 Contraindications

Use in patients with phaeochromocytoma.
Use in patients with uncorrected hypovolaemia.
Atrial or ventricular tachyarrhythmias.
Hyperthyroidism.

4.4 Special warnings and precautions for use

The degree of response to dopamine is reduced the longer the interval between onset of haemodynamic deterioration and treatment.

Dopamine should only be used under the direct supervision of physicians to whom facilities for regular, intensive monitoring of cardiovascular and renal parameters, in particular blood volume, myocardial contractility, cardiac output, electrocardiography, urine flow rate, blood and pulse pressure are available.

Inadvertent extravasation of drug may cause local necrosis. Local infiltration with phentolamine in saline solution should be given as soon as possible.

Dopamine should only be used with extreme caution in patients with a history or potential for occlusive vascular disease.

Since the effect of dopamine on impaired renal and hepatic function is not known, close monitoring is advisable.

Sodium Metabisulphite in this injection may rarely cause hypersensitivity reactions and bronchospasms.

Each ampoule of this injection contains 2.42mg sodium per ml.

4.5 Interaction with other medicinal products and other forms of interaction

Use of dopamine in patients who are receiving, or have received within two weeks, monoamine oxidase inhibitors will require reduction of dosage to avoid potentiation.

Dopamine should only be used with extreme caution in patients receiving cyclopropane or halogenated hydrocarbon anaesthetics because of potential for arrhythmias.

4.6 Fertility, pregnancy and lactation

The substance should only be used in pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable in view of the indications for use and the short half-life of the drug.

4.8 Undesirable effects

Side effects include tachycardia, anginal pain, ectopic beats, palpitation, dyspnoea, hypotension, vasoconstriction, headache, nausea and vomiting. Other adverse effects reported less frequently include bradycardia, aberrant conduction, azotaemia and piloerection.

4.9 Overdose

Hypertension and vasoconstriction are manifestations of sympathomimetic activity resulting from overdosage. Since the duration of action is short, adverse effects may be managed by discontinuing or reducing the rate of infusion as appropriate. If these measures fail, use of an alpha-adrenoceptor blocking agent such as phentolamine may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dopamine is a sympathomimetic agent with actions at alpha, beta and dopamine receptors. The type of receptor stimulated is determined by the dose. In relatively low doses, dopamine dilates renal and mesenteric blood vessels causing increases in renal blood flow, urine output and sodium excretion. As the dosage is increased, dopamine exerts a direct inotropic effect on the heart causing increases in cardiac output with minimal effects on the heart rate. With larger doses, dopamine also exerts alpha-stimulant effects, notably vasoconstriction.

5.2 Pharmacokinetic properties

Dopamine is inactive when taken orally and its vasoconstrictive properties preclude its administration by subcutaneous or intramuscular injection. It is rapidly inactivated in the body and the majority is metabolised into dopamine-related metabolic products which are rapidly excreted in the urine. The plasma half-life of dopamine is approximately 2 minutes.

5.3 Preclinical safety data

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite (E223)
Water for Injections

6.2 Incompatibilities

Dopamine should not be added to 5% Sodium bicarbonate or other alkaline solution because the drug will be inactivated.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6

6.3 Shelf Life

Product as packaged for sale : 3years

This solution must be diluted before use and used immediately after opening.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

For storage of opened and diluted product see section 6.3

6.5 Nature and contents of container

Clear glass one point-cut (OPC) ampoules, glass type I Ph.Eur. with white ring.
Pack size: 10 x 5ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only.

Discard any unused contents.

Do not use the injection if it is darker than slightly yellow or discoloured in any other way.

The solution must be diluted before use.

The usual dilution is 1,600 micrograms per ml.

Dopamine Hydrochloride can be diluted with 500ml of one of the following sterile intravenous solutions:

Sodium Chloride Injection

5% dextrose injection

5% dextrose and 0.9% Sodium

Chloride Injection

5% dextrose and 0.45%

Sodium Chloride solution

5% dextrose in Ringer Lactate Solution

Sodium Lactate 1/6 Molar injection

Lactated Ringers Injection

Do not dilute with alkaline solutions such as 5% sodium bicarbonate because the drug will be inactivated.

7 MARKETING AUTHORISATION HOLDER

Antigen Pharmaceuticals Limited

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8 MARKETING AUTHORISATION NUMBER

PA 0073/108/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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