

Sterile Dopamine Concentrate 200mg/5ml and 800mg/5ml

Dopamine Hydrochloride

Read all of this leaflet carefully before you start using Dopamine Concentrate because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dopamine Concentrate is and what it is used for
2. What you need to know before you take Dopamine Concentrate
3. How to take Dopamine Concentrate
4. Possible side effects
5. How to store Dopamine Concentrate
6. Contents of the pack and other information

1. What Dopamine Concentrate is and what it is used for

Dopamine is a medicine that stimulates the heart and has effects on the blood vessels.

Dopamine Concentrate can be used:

- to treat low blood pressure or shock (reduction of blood flow through the body tissues) after a heart attack, blood poisoning, trauma (injury).
- in combination with other treatments where low blood pressure occurs after open heart surgery.
- in congestive heart failure (heart failure due to a build-up of fluid/blood).

2. What you need to know before you take Dopamine Concentrate

Do not take Dopamine Concentrate if:

- you are allergic to Dopamine Hydrochloride or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- you have a tumour that causes an increase in blood pressure.
- you have a fast and irregular heartbeat.

If possible, tell your doctor if any of the above applies to you before this medicine is used.

Warnings and Precautions

Talk to your doctor or nurse before using Dopamine Concentrate.

Special care needs to be taken with Dopamine concentrate:

- if you have diabetes.
- if you have kidney or liver problems.
- if you have a history of blood circulation problems (you will be monitored for any changes in colour or temperature of your fingers or toes).
- if you have narrow angle glaucoma.
- if you have benign prostatic hyperplasia with urinary retention.
- if you have an overactive thyroid gland.
- you have recently used monoamine oxidase inhibitors (known as MAOIs which are used for the treatment of depression; see section "Taking other medicines" for further information).
- you are sensitive to sulphite.

If possible, tell your doctor if any of the above applies to you before this medicine is used.

Other medicines and Dopamine Concentrate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without prescription.

Special care is needed if you are using other medicines as some could interact with Dopamine Concentrate, for example:

- medicines used to treat depression such as amitriptyline.
- phenytoin, a medicine used to treat epilepsy.
- alpha- and beta-blockers, e.g. propranolol (medicines which are often used for treating blood pressure and heart disorders).
- ergotamine, a medicine used to treat headaches.
- guanethidine, a medicine used to treat high blood pressure.
- anaesthetics (dopamine should not be used with cyclopropane and halogenated hydrocarbon anaesthetics).
- Monoamine-Oxidase Inhibitors (MAOI), a type of medicine used to treat depression.
- reserpin, cardiac glucosides, metoclopramide.
- entacapone, a medicine used in Parkinson's disease.
- doxapram, used as a respiratory stimulant.
- antiarrhythmics.
- thyroid hormones.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Driving and using machines

Not applicable, as the drug product is to be administered at the hospital.

Dopamine Concentrate contains sodium metabisulphite

This excipient may rarely cause severe hypersensitivity (severe allergy) reactions and bronchospasm (breathing difficulties).

If you need to control your salt intake (controlled sodium diet) be aware that:

- Dopamine Concentrate contains 2.42 mg sodium in each ml of solution. This is equivalent to 0.12% of the recommended maximum daily dietary intake of sodium for an adult.
- The contents of the ampoule may be diluted in a salt solution before being given to you. This salt solution also contains sodium.

Continued overleaf

3. How to take Dopamine Concentrate

This medicine will be diluted before it is given to you. It will be given as an infusion (drip) into a vein.

Dose

If your blood volume is low, you may be given a transfusion of blood or a plasma expander before dopamine is given.

Your doctor will work out the correct dose of dopamine for you and how often it must be given. The dose will depend upon your medical condition and your size.

The rate of administration will be carefully controlled and adjusted according to your response. During treatment your heart rate, blood pressure and urine output will be measured to check how you are responding.

If you use more Dopamine Concentrate than you should

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, Dopamine Concentrate can cause side effects, although not everybody gets them.

One of the ingredients of this medicine may cause an allergic reaction (see section 2 of this leaflet 'Important information about some of the ingredients of this medicine'). Tell your doctor or nurse immediately if you experience any of the following symptoms:

- swelling of the face, lips or tongue
- wheezing or difficulty breathing
- rashes, red, raised lumps or itching

More common reactions include

Cardiovascular: Ectopic heart beats, racing heart (tachycardia), chest pain (anginal pain), palpitation, low blood pressure (hypotension) and narrowing of the small arteries (vasoconstriction).

Gastrointestinal: Feeling sick (nausea) and vomiting.

Nervous System: Headache, anxiety, tremor.

Respiratory: Laboured breathing (dyspnoea).

Renal and Urinary Disorders: Going to the toilet a lot (polyuria).

Investigations: Serum glucose level increased, BUN (Blood urea nitrogen) level increased.

Less common reactions include

Biochemical Abnormalities: Kidney failure (azotaemia).

Cardiovascular: Irregular transfer (aberrant conduction), slow heartbeat (bradycardia), widened QRS complex, high blood pressure (hypertension), gangrene, fatal ventricular arrhythmias (irregular heartbeat) have been reported on rare occasions.

Eye Disorders: Great dilatation of the pupil (mydriasis).

Nervous System: Hair standing on end (piloerection).

Serious or Life-threatening Reactions:

Gangrene of the extremities has occurred following higher doses and in lower doses patients with pre-existing vascular disease.

Dopamine may lead to changes in your blood chemistry. Your doctor may take blood samples to monitor for these.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website:

www.mhra.gov.uk/yellowcard or search for MHRA

Yellow card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dopamine Concentrate

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not use if the contents are discoloured.

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

Do not store above 25°C.

6. Contents of the pack and other Information

What Dopamine Concentrate contains

The active substance is dopamine hydrochloride the other ingredients are sodium metabisulphite, water for injections, hydrochloric acid and sodium hydroxide.

What Dopamine Concentrate looks like and the contents of the pack.

Dopamine Concentrate is a clear, colourless to pale yellow solution supplied in glass ampoules, each containing 5ml. The ampoules are supplied in packs of 10 ampoules.

Marketing Authorisation Holder


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