

Patient leaflet: Information for the patient

Sterile Dopamine Concentrate BP 160mg/1ml, 5ml dopamine hydrochloride

Read all of this leaflet carefully before you start being given this medicine 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Sterile Dopamine Concentrate BP 160mg/ml, 5ml. It will be referred to as “Dopamine Concentrate” for ease of use hereafter.

What is in this leaflet

1. What Dopamine Concentrate is and what it is used for
2. What you need to know before you are given Dopamine Concentrate
3. How Dopamine Concentrate is given to you
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

Sterile Dopamine Concentrate BP contains 800mg of dopamine hydrochloride per 5ml (160 mg in 1ml) which helps to improve the blood circulation following a heart attack, injury, blood poisoning, kidney failure, heart failure and open heart surgery.

2. What you need to know before you are given Dopamine Concentrate

You should not be given Dopamine Concentrate

- if you are allergic to dopamine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have high blood pressure due to a tumour near the kidney (phaeochromocytoma)
- if you have a rapid, irregular heart beat
- if you have an overactive thyroid gland
- if you are being given certain anaesthetics, such as halothane and cyclopropane

Warnings and precautions

Talk to your doctor or nurse before you are given Dopamine Concentrate

- if you have an obstruction of the blood vessels (e.g. hardening of the arteries)
- if you have a disease of the liver or kidneys
- if you are pregnant
- if you use or have recently used (within previous 2 weeks) a monoamine oxidase inhibitor (MAOI), which is a medicine for treating depression
- if you have diabetes

- 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 do not have enough fluid in the circulation (e.g. due to bleeding, vomiting or diarrhoea)

If you have any of the conditions mentioned above, tell your doctor before you receive this medicine.

Other medicines and Dopamine Concentrate

Tell your doctor if you are taking, have recently taken or might take any other medicines.

If you are already taking one of the following medicines, speak to your doctor before you receive this

- Anaesthetics (such as halothane, isoflurane or cyclopropane), alpha and beta blockers (eg propranolol) for blood pressure or heart disorders (e.g. Guanethidine)
- Phenytoin Injection for epilepsy
- Water tablets (Diuretics e.g. Acetazolamide)
- Ergot alkaloids for migraine (e.g. Dihydroergotamine).
- Monoamine oxidase inhibitors (used for the treatment of depression) (e.g. phenelzine, moclobemide, rasagiline, selegiline, entacapone)
- Tricyclic antidepressants used to treat depression such as (e.g. amitriptyline).

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 taking this medicine.

Dopamine Concentrate contains sodium metabisulphite

Sodium metabisulphite may rarely cause severe hypersensitivity (allergic) reactions & bronchospasm (breathing difficulties).

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. How Dopamine Concentrate is given to you

The solution must be diluted before use. Your doctor will decide on the most suitable dilution and dosage to meet your requirements. The diluted solution will be administered by drip into a vein.

Dosage for Adults:

Initially 2 to 5 micrograms per kilogram body weight per minute. This may be increased gradually by amounts of 10 to 15 micrograms per kilogram per minute to achieve the most suitable dose. Up to 50 micrograms per kilogram per minute may be required and even higher doses have been used.

Use in children and adolescents

Not recommended.

If you are given more Dopamine Concentrate than you should have

If you think that you may have been given too much of this medicine, tell your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- Abnormally fast heart rates (fatal ventricular arrhythmias)
- Severe irregular heartbeat
- Swelling, change in the skin color from red, to brown, to black, pus and a foul smell (gangrene) of feet.

Other side-effects

Not known: frequency cannot be estimated from the available data

- Rapid, slow or irregular heart beats
- Chest pain, awareness of a rapid or irregular pulse, low blood pressure (you may feel dizzy or faint, particularly when standing up or getting out of bed)
- Pain or poor circulation in your fingers or toes (you may notice a change in skin colour)
- Nausea, vomiting
- Headache
- Shortness of breath
- An excess of urea or other waste products in the blood (which may make you feel generally unwell and is identified by blood tests)
- Swelling, change in the skin color from red, to brown, to black, pus and a foul smell (gangrene)
- High blood pressure
- Dilation of the pupil of the eye (mydriasis) which may cause difficulty seeing in bright light
- Erection of the hair of the skin

If dopamine hydrochloride escapes from the blood vessel into the tissues during administration, it may cause tissue damage. Tell your doctor if you notice any pain or swelling at the injection site so that the appropriate treatment may be given.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. 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 carton and ampoule label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

This solution must be diluted before use and used immediately after opening. Do not dilute with alkaline solutions.

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

If only part used, discard the remaining solution.

For single use only.

6. Contents of the pack and other information

What Dopamine Concentrate contains

- The active substance is dopamine hydrochloride. Sterile Dopamine Concentrate BP 800mg in 5ml contains 800mg of dopamine hydrochloride per 5ml (160 mg in 1ml). It is for the preparation of dopamine hydrochloride intravenous infusion.
- The other ingredients are sodium metabisulphite (E 223) and water for injections.

What Dopamine Concentrate looks like and contents of the pack

Sterile Dopamine Concentrate BP is a clear, colourless or pale yellow solution presented in 5ml clear glass ampoules.

Pack Size: Each pack contains 10 x 5ml ampoules.

Type of medicine: Dopamine is called an inotropic medicine. Inotropic medicines increase the strength of muscle contraction in the heart.

Marketing Authorisation Holder

Mercury Pharmaceuticals (Ireland) Ltd 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

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