



Dopamine Hydrochloride Injection USP 400mg/10ml, 200mg/5ml.

Package Leaflet: Information for the user

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or nurse.

If any of the side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Dopamine Hydrochloride 40mg/ml Concentrate for Solution for Infusion. It will be referred to as “Dopamine Concentrate” for ease of use hereafter.

What is in this leaflet:

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

Dopamine Hydrochloride 40mg/ml Concentrate For Solution For Infusion contains 200mg of Dopamine Hydrochloride which helps to increase the strength of muscle contraction in the heart.

It is used to correct poor circulation to the tissues

- when there is a low output of blood from the heart and shock associated with damage to the heart muscle due to obstruction of its blood supply.
- also after an injury, blood infection, heart failure and open heart surgery.

2. What you need to know before you are given dopamine concentrate

You should not be given this medicine if:

- you are allergic to Dopamine hydrochloride or any other ingredients of this medicine (listed in section 6).
- you have been told by your doctor that you have a tumour of the adrenal gland (phaeochromocytoma).
- you have abnormal heartbeats and uncoordinated contraction of the heart muscles.
- you have an overactive thyroid gland.

Warnings and precautions

Talk to your doctor or nurse before using Dopamine Hydrochloride Injection if:

- you have any heart related problems

- 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
- you have a weaker pulse in your wrists than normal on examination
- you have a blood disorder in which the volume of circulating blood is decreased (hypovolaemia)
- you know that you are suffering or have suffered from problems related to circulation of blood in your hands and feet (peripheral vascular disease)
- you have any kidney or liver diseases
- you are pregnant or breast feeding
- you have diabetes

Speak to your doctor before you are given this injection if this applies to you.

Your doctor will monitor you for any side-effects affecting the heart or kidneys while you are receiving dopamine.

Dopamine infusion should be withdrawn gradually, to avoid low blood pressure.

Other medicines and Dopamine Concentrate

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

Some medicines can interact with Dopamine Concentrate, which can significantly alter their effects. If you are already

taking one of the following medicines, speak to your doctor before you receive this medicine:

- Monoamine oxidase inhibitors (used for the treatment of depression) or if you have taken them in the last 14 days, e.g. phenelzine, moclobemide, rasagiline, selegiline, entacapone.
- Water tablets (diuretics), e.g. furosemide, amiloride or triamterene.
- Medicines which are often used for treating blood pressure and heart disorders (alpha and beta blockers e.g. propranolol, tolazoline).
- Medicines used to treat epilepsy (phenytoin).
- Medicines used to treat migraine (e.g. ergotamine derived from ergot alkaloids, methysergide).
- Medicines used to treat depression such as Tricyclic antidepressants (e.g. amitriptyline).
- Medicines used to reduce high blood pressure like guanethidine.
- Medicine used to help your breathing (doxapram).
- Medicines used to treat psychological problems like schizophrenia (e.g. haloperidol, clozapine).

Tell your doctor before you are given Dopamine Hydrochloride Injection if you have recently received any anaesthetic agent such as halothane, isoflurane or cyclopropane.

Pregnancy and breast-feeding and fertility

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.

As with all drugs, this medicine should only be given in pregnancy and when breast feeding if absolutely necessary. Your doctor will be able to advise you.

Driving and using machines

Not applicable

Dopamine Hydrochloride Injection contains:

Sodium metabisulphite, which may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (breathing difficulties).

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

3. How Dopamine Hydrochloride Injection is given to you

This injection will be administered under the supervision of a doctor. The solution is diluted before administration and will then be given by infusion (as a drip through a needle or tube) into a vein.

Your doctor will decide on the most suitable dose for you. This product is not recommended for use in children.

If you think you have been given more Dopamine Hydrochloride Injection than you should have

As the injection will be administered under the supervision of a doctor, it is unlikely that you will be given more than is necessary. However, if you have any concerns about the dose of your medicine discuss them with your doctor.

If you develop symptoms like narrowing of the blood vessels, tissue death around blood vessels, restriction in blood supply due to tissue damage due to over use of this product your doctor will stop giving you this medicine and give you other medications for treatment.

If you have any further questions on the use of this medicine ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Dopamine Hydrochloride Injection can sometimes cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face, lips, rash or itching (especially affecting your whole body), should be reported to a doctor immediately.

Other side effects:

Common (may affect up to 1 in 10 people):

- headache
- a rapid or slow heart beat, chest pain, irregular heart beat and awareness of a rapid or irregular pulse
- difficulty in breathing
- low blood pressure (which may cause symptoms such as faintness or dizziness)
- narrowing of blood vessels (which may cause the skin to become cold and to turn pale or to have a bluish colour)
- nausea and vomiting

Uncommon (may affect up to 1 in 100 people):

- dilation of the pupil of the eye which may cause difficulty with bright lights
- shortness of breath
- goose pimples or hair 'standing at ends'
- pain in your fingers or toes (at higher doses, especially in people who have had problems with their circulation, gangrene can occur)
- abnormalities in the ECG (a tracing of electrical currents in the heart)
- high blood pressure.
- an excess of urea or other waste products in the blood (which may make you feel generally unwell and is identified by blood tests)

If dopamine hydrochloride escapes from the vein into the surrounding tissues during administration, it may cause damage of the surrounding tissues; 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.

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 printed on the ampoule and carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

If only part used, discard the remaining solution.

If the solution appears darker than slightly yellow or discoloured in any other way, it should be returned unused to the pharmacist.

6. Contents of the pack and other information

The active substance is dopamine hydrochloride.

The other ingredients are sodium metabisulphite in water for injections.

What Dopamine Hydrochloride Injection looks like and contents of pack

Dopamine Hydrochloride Injection is a clear, colourless or pale yellow solution presented in 5ml clear glass ampoules (small glass bottles).

Each 5ml ampoule contains 200mg Dopamine Hydrochloride.

There are ten 5ml ampoules packed in to one cardboard box.

7.Manufactured in India by:

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