

Package leaflet: Information for the user

Dopamine Hydrochloride 40 mg/ml Sterile Concentrate dopamine hydrochloride

Read all of this leaflet carefully before you start using 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.

What is in this leaflet

1. What Dopamine Hydrochloride 40 mg/ml Sterile Concentrate is and what it is used for
2. What you need to know before you use Dopamine Hydrochloride 40 mg/ml Sterile Concentrate
3. How to use Dopamine Hydrochloride 40 mg/ml Sterile Concentrate
4. Possible side effects
5. How to store Dopamine Hydrochloride 40 mg/ml Sterile Concentrate
6. Contents of the pack and other information

1. What Dopamine Hydrochloride 40 mg/ml Sterile Concentrate is and what it is used for

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

What is it used for?

Dopamine Hydrochloride Sterile 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) or kidney failure
- 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)

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Dopamine Hydrochloride 40 mg/ml Sterile Concentrate

Do not use Dopamine Hydrochloride

- if you are allergic to dopamine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have a tumour that causes an increase in blood pressure
- if you have an overactive thyroid gland
- if you have irregular or rapid heartbeats
- if you have shown signs of hypersensitivity (severe allergy) to dopamine or sodium metabisulphite in the past

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, pharmacist or nurse before using Dopamine Hydrochloride

- 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)
- in the elderly
- in children
- if you have low blood pressure (shock) due to a heart attack
- if you have low blood volume (your doctor will take steps to get your blood volume up to normal before giving you dopamine)

Children

The safety and efficacy of Dopamine Sterile Concentrate in children has not been established.

Other medicines and Dopamine Hydrochloride

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, for example:

- anaesthetics (dopamine must not be used with cyclopropane and halogenated hydrocarbon anaesthetics)
- alpha- and beta-blockers, e.g. propranolol (medicines which are often used for treating blood pressure and heart disorders)
- monoamine oxidase inhibitors and tricyclic antidepressants (medicines used to treat depression)
- phenytoin (a medicine used to treat epilepsy)
- water tablets (diuretics)
- ergot alkaloids (medicines used to treat migraine)
- guanethidine (a medicine used to reduce high blood pressure)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will only use this medicine if the expected benefits outweigh any potential risk to your baby.

Driving and using machines

Do not drive or use machines if you experience any side effect (e.g. dizziness or difficulty seeing in bright light) which may lessen your ability to do so.

Dopamine Hydrochloride 40 mg/ml Sterile Concentrate contains sodium metabisulphite and sodium

This medicine contains sodium metabisulphite which may rarely cause severe hypersensitivity (severe allergy) reactions and bronchospasm (breathing difficulties).

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

3. How to use Dopamine Hydrochloride 40 mg/ml Sterile Concentrate

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dosage and method of administration

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

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 are given too much or too little Dopamine Hydrochloride 40 mg/ml Sterile Concentrate

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

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

- severe allergic reaction - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- pain or poor circulation in your fingers or toes (you may notice a change in skin colour even to black (gangrene))
- severe palpitations

These are serious side effects. You may need urgent medical attention.

If any of the following happen, tell your doctor as soon as possible:

Common:

- irregular, rapid, or slow heart beats
- chest pain
- shortness of breath (this may be due to fluid in the lungs)
- low blood pressure (you may feel dizzy or faint, particularly when standing up or getting out of bed)
- narrowing of blood vessels (which may cause the skin to become cold and to turn pale or to have a bluish colour)
- feeling or being sick
- headache

Uncommon:

- high blood pressure (you may get headaches or your doctor may monitor for this)
- abnormalities in the ECG (a tracing of electrical currents in the heart)
- dilation of the pupil of the eye (mydriasis) which may cause difficulty seeing in bright light
- goose pimples

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance. Website: www.hpra.ie.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adportal

5. How to store Dopamine Hydrochloride 40 mg/ml Sterile 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 ampoule and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

Do not store above 30°C. Keep the ampoules in the outer carton in order to protect from light.

Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 48 hours provided they have been prepared in a way to exclude microbial contamination.

Visible signs of deterioration

Only clear, colourless or pale yellow solutions should be used. Opaque, cloudy or discoloured solutions should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dopamine Hydrochloride 40 mg/ml Sterile Concentrate contains

The active substance is dopamine hydrochloride. Each millilitre (ml) of concentrate contains 40 milligrams (mg) of dopamine hydrochloride.

The other ingredients are sodium metabisulphite and water for injections (see section 2 "Dopamine Hydrochloride 40 mg/ml Sterile Concentrate contains sodium metabisulphite and sodium").

What Dopamine Hydrochloride 40 mg/ml Sterile Concentrate looks like and contents of the pack

Dopamine Hydrochloride Sterile Concentrate is a clear, colourless or pale yellow concentrate for solution for infusion which comes in glass containers called ampoules.

It may be supplied in packs containing:

5 x 200 mg/5 ml ampoules

50 x 200 mg/5 ml ampoules

Not all packs may be marketed.

Marketing Authorisation Holder:

Ireland

Pfizer Healthcare Ireland
9 Riverwalk, National Digital Park
Citywest Business Campus
Dublin 24, Ireland

Malta

Pfizer Hellas S.A.
243 Messoghion Ave.
Neo Psychiko 15451,
Greece

Manufacturer:

Pfizer Service Company BV, Hoge Wei 10, 1930 Zaventem, Belgium

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Dopamine Hydrochloride 40 mg/ml Sterile Concentrate

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Dopamine Hydrochloride Sterile Concentrate should not be added to any alkaline intravenous solutions, i.e. sodium bicarbonate. Any solution which exhibits physical or chemical incompatibility through a colour change or precipitate should not be administered.

It is suggested that admixtures containing gentamicin sulphate, cephalothin sodium, cephalothin sodium neutral or oxacillin sodium should be avoided unless all other viable alternatives have been exhausted.

Admixtures of ampicillin and dopamine in 5% glucose solution are alkaline and incompatible and result in decomposition of both drugs. They should not be admixed.

Admixtures of dopamine, amphotericin B in 5% glucose solution are incompatible as a precipitate forms immediately on mixing.

Laboratory test interferences

Infusion of dopamine suppresses pituitary secretion of thyroid stimulating hormone, and prolactin.

Instructions for use and handling

For single use.

Discard any unused contents.

Do not use if the solution is discoloured.

Preparation of infusion solutions

Suggested dilution

Aseptically transfer Dopamine Hydrochloride Sterile Concentrate into the IV solution as shown in the following table:

Strength of Concentrate	Volume of concentrate (ml)	IV Solution Volume (ml)	Final Concentration (microgram/ml)
200 mg/5 ml	5	500	400
200 mg/5 ml	5	250	800
200 mg/5 ml	10	250	1600
200 mg/5 ml	20	500	1600

Dopamine hydrochloride can be diluted with:

- Sodium chloride (0.9%) solution
- Dextrose (5%), sodium chloride (0.45%) solution
- Sodium Lactate Intravenous Infusion, Compound (Hartmann's Solution for Injection)

A suitable metering device is required in the infusion system to control the rate of flow, and this should be adjusted to the optimum patient response and monitored constantly in the light of the individual patient's response.

In use storage precautions

Following dilution in the recommended diluents chemical and physical in-use stability has been demonstrated for 48 hours at a temperature not above 25°C.

However, from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C unless dilution has taken place in controlled and validated aseptic conditions.