

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Dopamine 40 mg/ml
Concentrate for solution for infusion
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 or nurse.
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT DOPAMINE IS AND WHAT IT IS USED FOR

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

Dopamine 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

Do not take Dopamine:

- 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 irregular or rapid heartbeats.

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.

Special care needs to be taken with Dopamine:

- 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.

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

Other medicines and Dopamine

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

- anaesthetics (dopamine should 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 (anti-depressant medicines).
- phenytoin (a medicine used to treat epilepsy).
- reserpin, cardiac glucosides, metoclopramide.
- thyroid hormones.
- antiarrhythmics.

Tell your doctor if you are using, have recently used or might use any other medicines.

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 contains sodium metabisulphite

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

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule, i.e. essentially 'sodium-free'.

3. HOW TO TAKE DOPAMINE

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



The following information is intended for healthcare professionals only:

Dopamine 40 mg/ml concentrate for solution for infusion
Dopamine hydrochloride

Incompatibilities

Dopamine concentrate for solution for infusion, 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.

Special precautions for disposal and other handling

For single use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Parenteral drug products should be visually inspected for particulate matter and discolouration prior to administration. Do not use if the injection is darker than slightly yellow or discoloured in any other way.

heart rate, blood pressure and urine output will be measured to check how you are responding.

If you use more Dopamine 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, this medicine can cause side effects, although not everybody gets them.

More common reactions include

Cardiovascular: Ectopic heart beats, racing heart (tachycardia), pain angina-related (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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOPAMINE

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

Do not use this medicine after the expiry date which is stated



Preparation of Infusion Solutions

Suggested Dilution

Aseptically transfer the sterile concentrate for solution for infusion into the IV solution as shown in the following table:

Strength of Concentrate (mg/ml)	Volume of concentrate (ml)	Volume of IV Solution (ml)	Final Concentration (microgram/ml)
40	5	500	400
40	5	250	800

Dopamine hydrochloride can be diluted with:

- 0.9% Sodium Chloride Injection
- 5% Glucose Injection
- 5% Glucose and 0.9% Sodium Chloride Injection
- 0.45% Sodium Chloride Solution
- 5% Glucose and 0.45% Sodium Chloride Solution
- 5% Glucose in Ringer Lactate Solution
- Sodium Lactate 1/6 Molar Injection
- Lactated Ringer's Injection

on the label and carton 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.

Parenteral drug products should be visually inspected for particulate matter and discolouration prior to administration. Do not use if the injection is darker than slightly yellow or discoloured in any other way.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dopamine contains

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

What Dopamine looks like and contents of the pack

Dopamine is a clear colourless to pale yellow solution packed in 5 ml clear, type I glass one point-cut (OPC) ampoules, packed in cardboard cartons.

Pack size: 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Hikma Farmacêutica (Portugal) S.A.
Estrada do Rio da Mó, nº8, 8A e 8B
Ferveça, 2705-906 Terrugem SNT, Portugal

Manufacturer

Hikma Italia S.P.A.
Viale Certosa, 10, 27100 Pavia, Italy

Distributed by:

Consilient Health (UK) Ltd.
No. 1 Church Road, Richmond upon Thames, Surrey,
TW9 2QE

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Dopamin Hikma 40 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Germany:	Dopamine Hikma 40 mg/ml, Konzentrat zur Herstellung einer Infusionslösung
Italy:	Dopamina Hikma
Portugal:	Dopamina Hikma
The Netherlands:	Dopamine Hikma 40 mg/ml, Concentraat voor oplossing voor infusie
United Kingdom:	Dopamine 40 mg/ml, Concentrate for solution for infusion

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