

## **Package leaflet: Information for the user**

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

#### **1. What Dopamine Sterile Concentrate is and what it is used for**

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

Dopamine Sterile Concentrate can be used in adults:

- 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)

#### **2. What you need to know before you use Dopamine Sterile Concentrate**

##### **Do not use Dopamine Sterile Concentrate**

- 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

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Dopamine Sterile 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 possible, tell your doctor if any of the above applies to you before this medicine is used.

## **Children**

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

## **Other medicines and Dopamine Sterile Concentrate**

Tell your doctor if you are taking, have recently taken or might take any other medicine, 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 (anti-depressant medicines)
- phenytoin (a medicine used to treat epilepsy)

## **Pregnancy, 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 or pharmacist for advice before taking this medicine.

## **Driving and using machines**

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

## **Dopamine Sterile Concentrate contains sodium metabisulfite (E 223)**

This medicine contains sodium metabisulfite which, rarely, may 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 Sterile 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 recommended 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 Sterile 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.

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

#### **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:**

Uncommon:

- 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)
- pain or swelling at the injection site during or immediately after the injection
- 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
- 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 via the Yellow Card System at: [www.mhra.gov.uk/yellowcard](http://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 Sterile Concentrate**

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

**Expiry date**

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 conditions**

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.

Do not use this medicine if you notice an opaque, cloudy or discoloured solution.

**6. Contents of the pack and other information**

**What Dopamine 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 metabisulfite (E 223) (see section 2 “Dopamine Sterile Concentrate contains sodium metabisulfite (E 223)”), water for injections, sodium hydroxide and hydrochloric acid.

**What Dopamine Sterile Concentrate looks like and contents of the pack**

Dopamine 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 pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, UK.

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**Dopamine 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 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 sulfate, 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.

### **Special precautions for disposal and handling**

For single use

Discard any unused contents

Do not use if the solution is discoloured

### **Preparation of infusion solutions**

#### **Dilution**

Aseptically transfer Dopamine 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%) intravenous infusion
- Dextrose (5%), sodium chloride (0.45%) solution
- Sodium lactate intravenous infusion, Compound (Hartmann's Solution for Injection)

### **Shelf life**

#### **In use**

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.