

## PACKAGE LEAFLET

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

**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.

The name of your medicine is Dopamine hydrochloride 40 mg/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 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**

Dopamine Concentrate contains dopamine hydrochloride which helps to increase the strength of muscle contraction in the heart.

It is 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 are given Dopamine Concentrate**

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

- If you are allergic to dopamine hydrochloride or any 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 you have an overactive thyroid gland

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Dopamine Concentrate if:

- you have any heart related problems
- you have a weaker pulse in your wrists than normal on examination
- 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)
- you know that you are suffering or have suffered from problems related to circulation of blood in your hands and feet (peripheral vascular disease)
- If you have any kidney or liver diseases
- If you have diabetes

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 Concentrate in children has not been established.

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

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

- Monoamine oxidase inhibitors (anti-depressant medicine)
- 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)
- Phenytoin (a medicine used to treat epilepsy)

### **Fertility, pregnancy and lactation**

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 Concentrate contains:**

This medicine contains potassium metabisulfite (E224); which may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains less than 1 mmol (39 mg) potassium per ampoule i.e. it is essentially 'potassium-free'.

This medicine contains less than 1 mmol (23 mg) of sodium per ampoule, i.e. it is essentially 'sodium-free'.

## **3. How Dopamine Concentrate is given to you**

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 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 Dopamine Concentrate 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 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'. When only a month and year is stated the expiry date refers to the last day of that month.

Store in the original package to protect the product from light. Do not freeze.  
Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 24 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 Concentrate contains**

The active substance is dopamine hydrochloride.  
Each millilitre (ml) of concentrate contains 40 milligrams (mg) of dopamine hydrochloride.  
The other ingredients are potassium metabisulfite (E224), sodium chloride, water for injections, sodium hydroxide (for pH-adjustment) and hydrochloric acid (for pH-adjustment).

### **What Dopamine Concentrate looks like and contents of pack**

The solution should be clear and colourless or pale brownish-yellow in a glass ampoule. Each ampoule contains 200 mg dopamine hydrochloride.  
There are 5 ampoules packed in a cardboard box.

### **Marketing authorisation holder**

S.A.L.F. S.p.A. Laboratorio Farmacologico via Marconi, 2 - 24069 Cenate Sotto (BG)  
Italy

### **Manufacturer**

S.A.L.F. S.p.A. Laboratorio Farmacologico via G. Mazzini, 9 - 24069 Cenate Sotto (BG)  
Italy

This leaflet was last revised in 08/2024.

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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 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.

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

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

Do not use if the solution is discoloured.

### Preparation of Infusion Solutions

#### Dilution:

Aseptically transfer the 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
- Ringer lactate

#### Laboratory test interferences

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

#### In-use Shelf life

Following dilution in the recommended diluents, chemical and physical in use stability has been demonstrated for 24 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.