

## PATIENT INFORMATION LEAFLET

### DOPASEL 200 mg/5 ml I.V. Ampoule Containing Concentrated Solution for Infusion

Sterile

The drug is slowly administered drop by drop into the vein.

- **Drug substance:** 1 ampoule containing 5 mL of solution contains 200 mg of dopamine hydrochloride (1 mL contains 40 mg of dopamine hydrochloride).
- **Excipients:** Sodium metabisulfite (E223), water for injection.

**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 pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.*
- *Tell your doctor that you are taking this medicine when you go to the doctor or hospital during the use of this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the recommended dosage.*

#### **What is in this leaflet:**

- 1. What DOPASEL is and what it is used for?***
- 2. What you need to know before you use DOPASEL***
- 3. How to use DOPASEL?***
- 4. What are the possible side effects?***
- 5. How to store DOPASEL***

***Headings are included.***

#### **1. What DOPASEL is and what it is used for?**

- DOPASEL is a drug that stimulates the heart and is effective on blood vessels. It is prepared by diluting to be given slowly dropwise intravenously.
- DOPASEL is contained in the ampoule. Each 5 mL ampoule contains 200 mg of dopamine hydrochloride. Each package contains 5 ampoules of 5 mL or 10 ampoules of 5 mL.
- DOPASEL contains a clear, colorless or light yellow solution in transparent ampoules.
- DOPASEL

-In the treatment of heart attack, blood poisoning, trauma (damage), kidney failure accompanied by low blood pressure (hypotension) or shock (reduced blood flow to tissues)

- In cases where low blood pressure occurs after open heart surgery in combination with

other treatments,

- It can be used in heart failure.

## **2. What you need to know before you use DOPASEL**

### **DO NOT USE DOPASEL**

If:

- You have a tumor that causes an increase in blood pressure,
- You have an overactive thyroid gland,
- You have an irregular or fast heartbeat,
- You have been given certain anesthetics such as halothane,
- You have had symptoms of hypersensitivity to dopamine or sodium metabisulfite.

Do not use DOPASEL.

### **USE DOPASEL CAREFULLY in the following cases**

If:

- You have diabetes,
- You have a blood circulation problem history (you will be followed up for any changes in color and temperature in your fingers and toes),
- You have kidney and liver failure,
- You have any heart problems,
- You have recently used monoamine oxidase inhibitors (drugs that prevent depression or drugs that lower blood pressure in people with high blood pressure),
- A significant decrease in pulse pressure is observed

*Please consult your physician if these warnings apply to you, even at any time in the past.*

### **Pregnancy**

*Consult your doctor or your pharmacist before using the drug.*

DOPASEL will be given during pregnancy only when absolutely necessary.

*If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or your pharmacist before using the drug.*

DOPASEL will be given during breastfeeding only when absolutely necessary.

### **Driving and using machines**

There are no data on any effects on the ability to drive and use machines.

### **Important information about some of the excipients contained in DOPASEL**

Allergic reactions (skin rash, swelling of the eyelid, face or lips, or difficulty breathing) because the drug contains sodium metabisulfite. This is rare, but if you suffer from allergies or asthma, you may be more at risk.

This product contains less than 1mmol (23 mg) of sodium in an ampoule, that is, it does not actually contain sodium.

### **Use with other medicines**

Certain drugs, such as the following drugs:

- Anesthetics (dopamine, cyclopropane and halogenated hydrocarbon should not be used in combination with anesthetics)
- Alpha and beta blockers such as propranolol (drugs often used to treat blood pressure and heart disorders),
- Monoamine oxidase inhibitors (antidepressant drugs),
- If you are taking phenytoin (a drug used to treat epilepsy), use DOPASEL with caution, because dopamine interacts with these drugs.
- Other drugs: it can increase the effect of drugs that increase urine excretion.
- Drugs containing ergo alkaloids, tricyclic antidepressants and guanetidine

*If you are currently using or taking any prescription or over-the-counter medication, please inform your doctor or pharmacist.*

### **3. How to use DOPASEL?**

#### **Instructions for appropriate use and dose / administration frequency:**

- The dose of medicine that will be given to you will be given according to your health condition, body weight and needs.
- The administration speed will be carefully controlled and adjusted according to your needs. Heart rate, blood pressure and urine output will be measured during treatment to determine the rate you need.

#### **Route and method of administration:**

- If you have low blood pressure, you may be given a blood transfusion or plasma expander before dopamine hydrochloride is given to you.
- DOPASEL will be diluted with eg 5% dextrose before being given to you. The medicine will be given to you slowly drop by intravenously, only diluted with physiological saline solution or 5%

glucose solution.

**Various age groups:**

**Use in children:**

The safety and effectiveness of dopamine in children is unknown.

**Use in the elderly:**

Dose adjustment is not recommended in the elderly. However, close monitoring is recommended for blood pressure and urine output.

**Special conditions of use:**

**Renal and hepatic failure:**

The effect of dopamine on kidney and liver failure is unknown. In this case, patients should be closely monitored.

*Please talk to your physician or pharmacist if you feel that the effect of DOPASEL is too strong or too weak.*

**If you have used more DOPASEL than you should**

*If you have used more DOPASEL than you should, talk a physician or pharmacist.*

Since DOPASEL will be administered to you in the hospital, you are unlikely to take more or less than necessary, but if you are concerned about this, consult your doctor or pharmacist.

**If you forget to use DOPASEL**

Your doctor will decide when to administer the missed dose.

It is important to follow your doctor's instructions for the new administration time of the following dose.

*Do not take a double dose to make up for forgotten doses.*

**Effects which may occur when treatment with DOPASEL is discontinued**

DOPASEL will be administered to you in the hospital by experienced healthcare personnel, the drug will be discontinued gradually in order to avoid unnecessary hypotension.

**4. What are the possible side effects?**

As with all medicines, there may be side effects in people who are sensitive to the ingredients of DOPASEL.

**If any of the following occur, stop using DOPASEL and IMMEDIATELY inform your doctor or apply to the nearest emergency department:**

Severe allergic reactions, sudden itchy rash; swelling of the hands, feet, ankles, face, lips, mouth, and throat (which can make it difficult to breathe or swallow) and feeling faint

These are all very serious side effects. If you have one of these, it means you have a serious allergy to DOPASEL. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

The frequency of adverse events is reported using the following categories.

<b>Very common</b>	: can be seen at least 1 of 10 patients.
<b>Common</b>	: can be seen less than one in 10 patients, but more than one in 100 patients.
<b>Uncommon</b>	: can be seen less than one in 100 patients, but more than one in 1,000 patients.
<b>Rare</b>	: can be seen less than one in 1.000 patients, but can be seen more than 10,000 patients in one.
<b>Very rare</b>	: can be seen less than one in 10,000 patients.
<b>Unknown</b>	: cannot be estimated from available data.

**Very common:**

- Headache
- Pupil growth
- Irregular heartbeat, increased heart rate (tachycardia), chest pain (angina), palpitations, low blood pressure
- Narrowing of veins
- Shortness of breath
- Nausea, vomiting

**Uncommon:**

- Horripilation
- Heart conduction disorders, heart rate slowdown
- Increased blood pressure
- Gangrene, foot gangrene (wounds)
- Heart rhythm disorders, tachycardia
- Increase in blood nitrogen (azotemia)

*If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.*

## **5. How to store DOPASEL**

*Keep DOPASEL out of the sight and reach of children, and in its packaging.*

Store at room temperature below 30°C, within protecting it from light. Use only clear solutions. Do not use fuzzy or precipitated solutions.

### **Use in compliance with the expiry date.**

*Do not use DOPASEL after the expiration date stated on the packaging.*

#### ***Marketing Authorization Holder:***

HAVER FARMA İlaç A.Ş.  
Akbaba Mah. Maraş Cad. No:52/2/1  
Beykoz /İSTANBUL

#### ***Manufacturing Site:***

Osel İlaç San. ve Tic. A.Ş.  
Akbaba Mah. Maraş Caddesi No:52  
Beykoz / İstanbul

*This patient information leaflet was approved on 02/09/2022.*