Patient leaflet according to Pharmacists' Regulations (Preparations), 1986
This medicine can be sold with a physician's prescription only.

DOPAMINE HYDROCHLORIDE S.A.L.F. 40mg/1ml

Concentrate for Solution for Infusion

The active ingredient:
Each 5 ml contain:
Dopamine Hydrochloride 200mg.
The inactive ingredients are listed in section 6.

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, ask the physician or pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

Dopamine hydrochloride S.A.L.F. 40mg/1ml is used for the treatment of states of shock of different nature:
- Post myocardial infarction cardiogenic shock, a shock caused by a heart attack.
- Surgical shock, caused by a surgical operation.
- Hypovolemic or haemorrhagic shock, caused by a decrease in blood volume due to a hemorrhage.

Therapeutic group:
Adrenergic and Dopaminergic agents.

A shock is characterized by a sharp decrease in blood pressure in response to a reduced blood flow in the organism.

2. Before using the medicine:

Do not use the medicine:
• If you are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine.
• If you have pheochromocytoma (adrenal gland cancer).
• If you suffer from hyperthyroidism (overactive thyroid).
• If you have abnormal heart rate (untreated tachyarrhythmia or ventricular fibrillation).
• Cyclopropane and halogenated hydrocarbon anesthetics should not be used together with dopamine during anesthesia.

Special warnings regarding the use of this medicine:
Consult your doctor before you start using Dopamine hydrochloride S.A.L.F. 40mg/1ml.
Take special care in the following cases:
• If you have a low blood volume (hypovolemia).
• If you have suffered from problems with blood flow and obstructive blood vessels diseases (atherosclerosis, arterial embolism, Raynaud's disease, cold injuries, blood flow problems due to diabetes (diabetic endarteritis) and Buerger's disease). In this case, any changes in the color or temperature of your fingers should be closely monitored.
• If you are treated with MAOIs (Monoamine Oxidase Inhibitors, medicines for the treatment of depression).

The medicine will be injected into your vein by a doctor or nurse. Infusion into the large veins is preferable, preventing the loss of the drug from the vein (extravasation) and reducing the risk of tissue damage (necrosis).
During dopamine injection, some parameters of the heart (cardiac output and blood pressure) and renal function (urine flow) should be monitored continuously.

Special warnings for athletes:
The use of this medicine without a legitimate medical reason is considered to be doping and can influence the outcome of anti-doping tests.

Children:
There is no information on the safety and efficacy of this medicine in children.

Use with other medicines:
Inform your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without a prescription. Especially inform your doctor if you are taking the following medicines:
• Monoamine Oxidase Inhibitors (MAOIs, a group of medicines used to treat depression).
• medicines used during anesthesia such as Cyclopropane and halogenated hydrocarbon anesthetics.
• Alpha and beta blockers used to lower blood pressure such as propranolol and metoprolol.
• Phenytoin, used to treat epilepsy.
• Medicines used to treat high blood pressure (diuretics, guantidine) and tricyclic antidepressants.
• Medicines for the treatment of migraine (ergot alkaloids).

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before using this medicine.
If you are pregnant or breastfeeding, this medicine should be used only when absolutely necessary and under medical supervision.

Driving and use of machinery:
This medicine will not affect your ability to drive or operate machines.

Important information about some of the ingredients of this medicine:
Dopamine hydrochloride S.A.L.F. 40mg/1ml contains potassium metabisulfite and sodium.
Potassium metabisulfite can in rare cases, cause acute allergic reactions and bronchospasm.
This medicine contains less than 1mmol (23mg) of sodium per ampoule, so it is essentially sodium-free.

3. How to use this medicine:
This medicine will be injected to you by medical personnel. If you have any questions regarding the use of this medicine, consult your doctor or nurse.
This medicine is injected into the vein (intravenously) after appropriate dilution.

Do not exceed the recommended dose.

If you have accidentally taken a higher dosage
An overdose is unlikely because this medicine is injected by medical personnel.
In case of an overdose, you may experience a sharp increase in blood pressure, which can be resolved by stopping or reducing the infusion.
The antidote is phentolamine mesylate.
If you think you are receiving too much medicine, talk to your doctor or nurse immediately.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult a physician or a nurse.

4. Side effects
Like any medicine, the use of this medicine may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
The following side effects may occur:
- Irregular heart rate (ectopic beats, tachycardia, ventricular conduction disorder, widening of QRS complex).
- Feeling of an increase in heart rate (palpitations).
- Slow heart rate (bradycardia).
- Chest pain due to heart problems (angina).
- Problems with blood flow caused by the narrowing of blood vessels (vasoconstriction).
- Increase or decrease in blood pressure.
- Nausea and vomiting.
- Headache.
- Shortness of breath (dyspnea).
- Goosebumps (piloerection).
- Increase in blood nitrogen levels.

If you experience any of these side effects, if a side effect becomes severe or if you suffer from a side effect not listed in the leaflet, consult your doctor.

Reporting side effects:
You can report side effects to the Ministry of Health by clicking the "report side effects due to medication" in the homepage of the Ministry of Health (www.health.gov.il) referring to an online form for reporting side effects, or by clicking the link: http://sideeffects.health.gov.il.

5. How to store the medicine
• Avoid poisoning! This medicine, and any other medicine, should be stored in a closed place out of the reach of children and/or infants, to avoid poisoning.
Do not induce vomiting unless explicitly instructed to do so by the physician.
• Do not use the medicine after the expiry date (exp. Date) stated on the package. The expiry date refers to the last day of that month.
• Store in the original package in order to protect from light. Do nor freeze.
• Store at a temperature under 25°C.

6. Additional information
In addition to the active ingredient, this medicine also contains:

Sodium chloride, Potassium metabisulfite, Water for injections**.**

What does the medicine look like and what does the package contain:
Dopamine hydrochloride S.A.L.F. 40mg/1ml is a concentrate for solution for infusion.
Each pack contains 5 glass ampoules of 5ml.

Medicine registration number:
164-32-35059-00.

Manufacturer:
S.A.L.F. S.p.A., Cenate Sotto, Italy.

Registration holder:
RAZ pharmaceutics LTD., 6 Hamatechet St., Kadima, Israel.

Approved in: April 2020

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