

Approved Patient Information Leaflet for Dopamine HCl 200 mg/5 ml Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DOPAMINE HCl 200 mg/5 ml FRESENIUS solution for infusion

Dopamine hydrochloride

Sugar free

Read all of this leaflet carefully before you receive DOPAMINE HCl 200 mg/5 ml FRESENIUS:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet:

1. What DOPAMINE HCl 200 mg/5 ml FRESENIUS is and what it is used for
2. What you need to know before you receive DOPAMINE HCl 200 mg/5 ml FRESENIUS
3. How to receive DOPAMINE HCl 200 mg/5 ml FRESENIUS
4. Possible side effects
5. How to store DOPAMINE HCl 200 mg/5 ml FRESENIUS

6. Contents of the pack and other information.

1. What DOPAMINE HCl 200 mg/5 ml FRESENIUS is and what it is used for

DOPAMINE HCl 200 mg/5 ml FRESENIUS contains dopamine hydrochloride which is a medicine that stimulates your heart and has an effect on the blood vessels.

Your doctor will give DOPAMINE HCl 200 mg/5 ml FRESENIUS to you in the hospital to:

- Treat shock (if you do not respond to the replacement of fluid loss and especially if you have a kidney disorder).
- Correct blood circulation to the tissues after a heart attack, injury, septic shock and heart surgery.
- Manage chronic congestive heart failure (heart failure due to a build-up of fluid/blood).

2. What you need to know before you receive DOPAMINE HCl 200 mg/5 ml FRESENIUS

DOPAMINE HCl 200 mg/5 ml FRESENIUS should not be given to you if you:

- Are hypersensitive (allergic) to dopamine hydrochloride or any of the other ingredients of DOPAMINE HCl 200 mg/5 ml FRESENIUS (listed in section 6 of this leaflet).
- Are pregnant or breastfeeding your baby.
- Are a child, as the safety and efficacy of DOPAMINE HCl 200 mg/5 ml FRESENIUS in children have not been established.
- Are using, or have used in the last 14 days, medicines called monoamine oxidase inhibitors (known as MAOIs, which are used for the treatment of depression) (see section "Other medicines and DOPAMINE HCl 200 mg/5 ml FRESENIUS").
- Have a phaeochromocytoma (a tumour of the medulla of the adrenal glands which secretes excessive amounts of catecholamines, usually noradrenaline and adrenaline).

- Suffer from tachycardia (irregular fast heartbeat).
- Suffer from ventricular fibrillation (uncoordinated contraction of the muscle of the ventricles in the heart).

Warnings and precautions:

Tell your doctor before you receive DOPAMINE HCl 200 mg/5 ml FRESSENIUS:

- If you have an overactive thyroid gland.

Take special care with DOPAMINE HCl 200 mg/5 ml FRESSENIUS if you:

- Have diabetes (high blood sugar).
- Have kidney or liver problems.
- Have heart or blood circulation disorders (irregular heartbeat, quick heartbeat, problems of high blood pressure or aneurysm (weak area with abnormal dilatation of a blood vessel)).
- Observe any changes in colour or temperature of your fingers or toes.
- Have narrow angle glaucoma (eye condition in which the intraocular pressure is increased).
- Have benign prostatic hyperplasia with urinary retention.
- Receive anaesthetics for an operation, such as cyclopropane and halothane.

Children and adolescents:

DOPAMINE HCl 200 mg/5 ml FRESSENIUS should not be given to children, as the safety and efficacy have not been established (see section "DOPAMINE HCl 200 mg/5 ml FRESSENIUS should not be given to you").

Other medicines and DOPAMINE HCl 200 mg/5 ml FRESSENIUS:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- Anaesthetics, e.g. halothane (used as an anaesthetic for operations).
- Tricyclic antidepressants (e.g. amitriptyline) or monoamine oxidase (MAO) inhibitors (e.g. tranylcypromine), used in the treatment of depression.
- Beta adrenergic blocking medicines, e.g. propranolol (used to regulate heartbeats and to reduce blood pressure).
- Digitalis glycosides, e.g. digoxin (used to treat congestive heart failure).
- Ergot derivatives, e.g. ergotamine (used in the prevention of migraine).
- Phenytoin (intravenous) (used in the treatment of epilepsy/fits).

DOPAMINE HCl 200 mg/5 ml FRESENIUS with food and drink:

There are no known interactions between DOPAMINE HCl 200 mg/5 ml FRESENIUS, food and drink.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving DOPAMINE HCl 200 mg/5 ml FRESENIUS.

Do not receive DOPAMINE HCl 200 mg/5 ml FRESENIUS if you are pregnant or breastfeeding your baby.

Driving and using machines:

Take special care when driving and using machines, until you know how DOPAMINE HCl 200 mg/5 ml FRESINIUS will affect you.

DOPAMINE HCl 200 mg/5 ml FRESINIUS contains potassium metabisulphite:

Potassium metabisulphite may cause severe hypersensitivity (allergic) reactions and bronchospasm (which makes it hard to breathe and cause wheezing). Please see section 4 "Possible side effects".

3. How to receive DOPAMINE HCl 200 mg/5 ml FRESINIUS

You will not be expected to give yourself DOPAMINE HCl 200 mg/5 ml FRESINIUS. It will be given to you by a doctor or a person who is qualified to do so.

DOPAMINE HCl 200 mg/5 ml FRESINIUS is a concentrated solution and must firstly be diluted, then injected intravenously (into one of your veins).

If your blood volume is low, you may receive a transfusion of blood or a plasma expander before DOPAMINE HCl 200 mg/5 ml FRESINIUS is given.

Your doctor or professional health care provider will carefully control the rate of administration and adjust it according to your response. He/she will measure your heart rate, blood pressure and urine output to check how you respond.

Your doctor will tell you how long your treatment with DOPAMINE HCl 200 mg/5 ml FRESENIUS will last. If you have the impression that the effect of DOPAMINE HCl 200 mg/5 ml FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more DOPAMINE HCl 200 mg/5 ml FRESENIUS than you should:

Since a health care provider will administer DOPAMINE HCl 200 mg/5 ml FRESENIUS, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdose.

If you forget to receive DOPAMINE HCl 200 mg/5 ml FRESENIUS:

Since a health care provider will administer DOPAMINE HCl 200 mg/5 ml FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

DOPAMINE HCl 200 mg/5 ml FRESENIUS can have side effects.

Not all side effects reported for DOPAMINE HCl 200 mg/5 ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DOPAMINE HCl 200 mg/5 ml FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving DOPAMINE HCl 200 mg/5 ml FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Wheezing.

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DOPAMINE HCl 200 mg/5 ml FRESSENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Narrowing of blood vessels (you may have a cold, bluish skin) and gangrene (tissue death due to interrupted blood supply).
- Severe heart palpitations (feeling that your heart is pounding or racing), other heart symptoms with chest pain, abnormal heartbeat.
- Irregular heartbeat, which may cause dizziness, shortness of breath, light-headedness, loss of consciousness or fainting.
- High blood pressure (hypertension).
- Chest pain.
- Swelling in the lungs (you may have extreme shortness of breath) or dyspnoea (difficulty in breathing).
- Dilatation of the pupil (large black dot) of the eye which may cause difficulty with bright lights.
- Going to the toilet a lot and passing excessive or abnormally large amounts of urine every time you urinate.
- High concentration of urea or other waste products in your blood if your kidneys are affected. You may, for example, feel unwell, tired, and nauseous. Your doctor may take blood samples to monitor your kidney function.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, anxiety (intense worrying), tremor (trembling).
- Nausea (feeling sick) and vomiting (being sick).
- Low blood pressure (you may feel faint or dizzy).

Less frequent side effects:

- Sweating, goose bumps with “hair standing at ends”.
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If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DOPAMINE HCl 200 mg/5 ml FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine’s regulatory authority in the country where the product is marketed.

5. How to store DOPAMINE HCl 200 mg/5 ml FRESENIUS

- Store at or below 30 °C.
- Protect from light.
- Do not use if darker than slightly yellow or discoloured in any other way.

- DOPAMINE HCl 200 mg/5 ml FRESENIUS is stable for at least 24 hours after dilution in saline or dextrose.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOPAMINE HCl 200 mg/5 ml FRESENIUS contains:

The active ingredient is dopamine hydrochloride.

Each 5 ml ampoule of DOPAMINE HCl 200 mg/5 ml FRESENIUS contains 200 mg dopamine hydrochloride.

The other ingredients are hydrochloric acid (for pH-adjustment), potassium metabisulphite and water for injections.

What DOPAMINE HCl 200 mg/5 ml FRESENIUS looks like and contents of the pack:

Clear colourless to slightly yellow solution in clear 5 ml ampoules.

5 ml clear Type 1 glass OPC ampoule with blue dot, packed into a PVC blister tray and outer carton.

Pack size: 10 ampoules per outer carton.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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