

## Approved Patient Information Leaflet for DOBUTAMINE 250 mg/20 ml FRESENIUS

### SCHEDULING STATUS

**S4**

### **DOBUTAMINE 250 mg/20 ml FRESENIUS**

**Concentrate for solution for infusion**

**Dobutamine as dobutamine hydrochloride**

**Sugar free.**

**Read all of this leaflet carefully before you are given DOBUTAMINE 250 mg/20 ml FRESENIUS.**

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

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

1. What DOBUTAMINE 250 mg/20 ml FRESENIUS is and what it is used for
2. What you need to know before you receive DOBUTAMINE 250 mg/20 ml FRESENIUS
3. How DOBUTAMINE 250 mg/20 ml FRESENIUS will be administered to you
4. Possible side effects
5. How to store DOBUTAMINE 250 mg/20 ml FRESENIUS
6. Contents of the pack and other information.

#### **1. What DOBUTAMINE 250 mg/20 ml FRESENIUS is and what it is used for**

DOBUTAMINE 250 mg/20 ml FRESENIUS is indicated in adults to increase contractility of the heart in the treatment of heart failure.

## **2. What you need to know before you receive DOBUTAMINE 250 mg/20 ml FRESENIUS**

### **Do not receive DOBUTAMINE 250 mg/20 ml FRESENIUS:**

- If you are hypersensitive (allergic) to dobutamine, sodium metabisulphite or any of the other ingredients of DOBUTAMINE 250 mg/20 ml FRESENIUS (listed in section 6).
- If you have been diagnosed with idiopathic hypertrophic subaortic stenosis. This is an inherited condition where your heart muscle becomes thick, causing it to work harder to pump blood out of your heart.
- If you are pregnant or breastfeeding your baby.
- If you have phaeochromocytoma (a rare tumour of the adrenal gland).

### **Warnings and precautions**

#### **Tell your doctor or healthcare provider before being given the injection:**

- if you have an irregular heartbeat
- if you are going to receive anaesthesia (before an operation or surgery)
- if you have lost a lot of fluid (for example, with diarrhoea or vomiting)
- if you had a heart attack, or a serious coronary heart disease
- if you have a heart or blood vessel disorder, in which DOBUTAMINE 250 mg/20 ml FRESENIUS should not be used to detect poor blood supply to your heart
- if you have asthma or if you have been told that you are allergic to sulphites (see “**DOBUTAMINE 250 mg/20 ml FRESENIUS contains sodium metabisulphite**” below)
- if you are currently treated for hypertension (high blood pressure), or if you have recently been treated for it.

### **Other medicines and DOBUTAMINE 250 mg/20 ml FRESENIUS**

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

**Tell your doctor if you take or receive the following:**

- anaesthetics (used before an operation or surgery, such as cyclopropane, halothane and other halogenated anaesthetics)
- entacapone (used to treat Parkinson's disease)
- beta-blockers (used to relieve certain heart conditions, anxiety or migraine, such as propranolol)
- beta-blockers with alpha-blocking effects (used to treat high blood pressure, such as carvedilol).

**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 healthcare provider for advice before DOBUTAMINE 250 mg/20 ml FRESENIUS is administered to you.

**Driving and using machinery**

You should not drive a vehicle or use machinery if you are affected by the administration of DOBUTAMINE 250 mg/20 ml FRESENIUS.

**DOBUTAMINE 250 mg/20 ml FRESENIUS contains sodium metabisulphite**

DOBUTAMINE 250 mg/20 ml FRESENIUS contains sodium metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

**3. How DOBUTAMINE 250 mg/20 ml FRESENIUS will be administered to you**

Your doctor will tell you how long your treatment with DOBUTAMINE 250 mg/20 ml FRESENIUS will last.

If you have the impression that the effect of DOBUTAMINE 250 mg/20 ml FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

**DOBUTAMINE 250 mg/20 ml FRESENIUS will be administered to you intravenously.**

You will not be expected to give yourself DOBUTAMINE 250 mg/20 ml FRESENIUS. It will be given to you by a person who is qualified to do so.

**If you receive more DOBUTAMINE 250 mg/20 ml FRESENIUS than you should:**

Since a healthcare provider will administer DOBUTAMINE 250 mg/20 ml FRESENIUS, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

**If you missed a dose of DOBUTAMINE 250 mg/20 ml FRESENIUS:**

Since a healthcare provider will administer DOBUTAMINE 250 mg/20 ml FRESENIUS, it is unlikely that the dose will be missed.

#### **4. Possible side effects**

DOBUTAMINE 250 mg/20 ml FRESENIUS can have side effects.

Not all side effects reported for DOBUTAMINE 250 mg/20 ml FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving DOBUTAMINE 250 mg/20 ml FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

**If any of the following happens, stop receiving DOBUTAMINE 250 mg/20 ml FRESENIUS and tell your doctor immediately:**

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DOBUTAMINE 250 mg/20 ml FRESINIUS. You may need urgent medical attention.

**Tell your doctor immediately if you notice any of the following:**

- heart attack (myocardial infarction)
- chest pain (angina)
- inflammation of the heart muscle in heart transplant patients
- uncontrolled contractions of the ventricles of the heart (ventricular tachycardia)
- shortness of breath.

Your doctor will examine your heart before administering DOBUTAMINE 250 mg/20 ml FRESINIUS to you (see “**Tell your doctor or healthcare provider before being given the injection**”).

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:***

- increase in white blood cells (eosinophilia)
- blood clotting problems
- headache
- irregular heart beat (palpitations)
- increase in heart rate
- non-specific chest pain
- blood pressure increase or decrease
- narrowing of the blood vessels (vasoconstriction, characterised by a change in the colour of your skin, cramps, headache).

***Less frequent side effects:***

- slow heartbeat (bradycardia)
- not enough blood supplied to the heart (myocardial ischaemia; you may feel pressure in your chest, shoulder or arm pain and a fast heartbeat)
- low blood potassium level (hypokalaemia)
- leg cramps (you may have low potassium levels)
- low blood pressure (you may feel dizzy when getting up).

***Frequency unknown:***

- feeling of heat
- anxiety
- restlessness
- sensation of tickling, prickling or numbness of your skin
- tremor (shaking)
- muscle cramps
- nausea (feeling sick)
- vomiting
- fever
- increased desire to urinate (at high doses), difficulty to urinate.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

Healthcare 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](mailto:safety.fksa@fresenius-kabi.com) and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the “**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 DOBUTAMINE 250 mg/20 ml FRESENIUS.

## **5. How to store DOBUTAMINE 250 mg/20 ml FRESENIUS**

- Store at or below 25 °C.
- Protect from light.
- Store all medicines out of reach of children.
- In combination with intravenous formulations it may be stored for 24 hours at or below 25 °C if dilution takes place under strict aseptic conditions. If dilution does not take place under strict aseptic conditions, the diluted solution is stable for a maximum of 24 hours at 2 – 8 °C (in a refrigerator), or 12 hours at or below 25 °C (room temperature), seen from a microbiological point of view.
- Do not freeze.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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

### **What DOBUTAMINE 250 mg/20 ml FRESENIUS contains:**

The active substance is dobutamine hydrochloride.

Other ingredients are:

Hydrochloric acid 10 % *m/v* (for pH-adjustment)

Sodium hydroxide 10 % *m/v* (for pH-adjustment)

Sodium metabisulphite 0,02 % *m/v*

Water for injection.

**What DOBUTAMINE 250 mg/20 ml FRESENIUS looks like and contents of the pack:**

Clear, colourless to slightly pink solution in a 20 ml clear, colourless glass ampoule.

Pack sizes: 1 or 5 ampoules.

**Holder of Certificate of Registration:**

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street

Midrand

1685

South Africa

Tel: 011 545 0000

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