Dobutamine Injection USP 250mg/5ml, 250mg/20ml

(Dobutamine)

Package Leaflet: Information for the user

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dobutamine is and what it is used for

Dobutamine belongs to a group of medicines known as inotropes, which make your heart beat more strongly.

In adults it is used:

- in open heart surgery
- to treat heart disease
- to treat heart failure
- in shock
- as an alternative to exercise for stress testing the heart.

Paediatric population

Dobutamine is indicated in all paediatric age groups (from neonates to 18 years of age) as inotropic support in low cardiac output hypoperfusion states resulting from decompensated heart failure, following cardiac surgery, cardiomyopathies and in cardiogenic or septic shock.

2. What you need to know before you are given Dobutamine Concentrate

You should not be given Dobutamine if you:

- are allergic to Dobutamine, sodium metabisulfite or any of the other ingredients in this injection.
- suffer from high blood pressure due to a tumour near the kidney (Phaeocromocytoma).
- have certain heart or blood vessel disorders. Dobutamine should not be used to detect poor blood supply to your heart (a cardiac stress test known as Dobutamine Stress Echocardiography)

Warnings and precautions:

Talk to your doctor or nurse if you have any of the following conditions:

- have recently had a heart attack
- have had a heart transplant
- are asthmatic
- have unstable angina
- have heart disease
- have high blood pressure
- have any condition that would make exercise dangerous for you.

Children

Increments in heart rate and blood pressure appear to be more frequent and intense in children than in adults. The new-born baby cardiovascular system has been reported to be less sensitive to dobutamine and hypotensive effect (low blood pressure) seems to be more often observed in adult patients than in small children. Accordingly, the use of dobutamine in children should be monitored closely.

Other medicines and Dobutamine Concentrate:

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Dobutamine Concentrate:

beta blockers (medicines used to relieve certain heart conditions, anxiety and migraine).

anaesthetics.

entacapone (a medicine to treat Parkinson's Disease).

Pregnancy and breast feeding:

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:

You should not drive or use machinery if you are affected by the administration of Dobutamine Concentrate.

3. How Dobutamine is given

Your nurse or doctor will give you the injection. Your doctor will decide the correct dosage for you

and how and when the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, feel sick, are sick, feel anxious, feel palpitations, have a headache, feel short of breath or have chest pain you must tell the person giving you the injection.

Use in Children

Your child will be given the injection by a nurse or doctor who will decide the correct dosage for your child and how and when the injection will be given.

If you have any further questions or concerns on the use of this medicine for your child ask the doctor or nurse giving the injection.

4. Possible side effects

Like all medicines, Dobutamine can cause side effects, although not everybody gets them.

Your doctor will examine your heart before giving you Dobutamine to decide if you are suitable to receive the drug.

The following side-effects have been reported:

Very common (more than 1 in 10 patients)

- increased heart rate
- chest pain
- heartbeat disturbances

Common (in less than 1 in 10, but more than 1 in 100 patients)

- blood pressure increase or decrease
- narrowing of the blood vessels (vasoconstriction)
- irregular heartbeat (palpitations)
- asthma-like symptoms (bronchospasm)
- shortness of breath
- increase in white blood cells (eosinophilia)
- inhibition of blood clot formation
- rash (exanthema)
- fever
- inflammation of the vein at the injection site
- (phlebitis)

Uncommon (in less than 1 in 100, but more than 1 in 1000 patients)

fast contractions of the ventricles of the heart (ventricular tachycardia)

uncontrolled contractions of the ventricles of the heart (ventricular fibrillation)
heart attack (myocardial infarction)

Very rare (in less than 1 in 10 000, including isolated cases)
slow heartbeat (bradycardia)
not enough blood supplied to the heart (myocardial ischaemia)
low potassium (hypokalaemia)
spots on the skin (petechial bleeding)
heart block
narrowing of the blood vessels supplying the heart (coronary vasospasm)

Not known (cannot be estimated from the available data)

- chest pain caused by stress (stress cardiomyopathy)
- allergic reactions (hypersensitivity reactions) including

symptoms of rash, fever, increase in white blood cells (eosinophilia) and asthma-like symptoms (bronchospasm)
- severe allergic reactions (anaphylactic reactions) and severe life-threatening asthmatic episodes possibly due to sensitivity to sodium metabisulfite (see Section 2)
- muscle cramp (myoclonus) in patients with severe renal failure receiving dobutamine
- abnormal heart function test (electrocardiogram ST segment elevation)
- inflammation of heart muscle (eosinophilic
- myocarditis) in heart transplant patients
- heart block (left ventricular outflow tract
- obstruction)
- fatal heart rupture
- restlessness
- feeling sick (nausea)
- headache
- pins and needles (paraesthesia)
- tremor
- increased desire to urinate (at high doses)
- feelings of heat and anxiety
- muscle cramp (myoclonic spasm)

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.

5. How to store Dobutamine

Your doctor and pharmacist are responsible for the correct storage, use and disposal of this medicine.

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 carton/label. The expiry date refers to the last day of the month.

Do not use this medicine if you notice the solution is not clear and free of particles or if the container is damaged.

Your pharmacist will dispose of any medicine that remains unused.

6. Contents of the pack and other information

What Dobutamine contains: The active ingredient is dobutamine hydrochloride. Each 1 ml contains dobutamine hydrochloride equivalent to 12.5 mg dobutamine in a sterile solution for injection.

The other ingredients are sodium metabisulfite, sodium hydroxide, hydrochloric acid, sterile water for injections and carbon dioxide.

What Dobutamine looks like and contents of the pack:

Dobutamine is supplied in 20 ml clear glass ampoules, in cartons containing one, five or ten ampoules. Not all sizes may be marketed.

7.Manufactured in India by:

TAJ PHARMACEUTICALS LTD.
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