Package leaflet: Information for the patient

Dobutamine 12.5mg/ml Concentrate for Solution for Infusion
Dobutamine Hydrochloride

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 nurse.
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.
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Dobutamine 12.5mg/ml Concentrate for Solution for Infusion, it will be referred to as Dobutamine Concentrate throughout the leaflet for ease here after.

What is in this leaflet:
1. What Dobutamine Concentrate is and what it is used for
2. What you need to know before you are given Dobutamine Concentrate
3. How you will be given Dobutamine Concentrate
4. Possible side effects
5. How to store Dobutamine Concentrate
6. Contents of the pack and other information

1. What Dobutamine Concentrate is and what it is used for

Dobutamine belongs to a group of medicines known as inotropic drugs, which support your heart to beat strongly in conditions where it is not able to pump adequate blood.

It is used in the treatment of heart failure associated with
• a heart attack
• open heart surgery
• heart muscle disease of unknown cause (cardiomyopathies)
• shock due to heart disease (septic shock or cardiogenic 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 Concentrate:
• if you are allergic to dobutamine hydrochloride or any of the other ingredients in this medicine (listed in section 6)
• if you are allergic to sodium metabisulphite
• if you have an obstruction that interferes with blood flow out of your heart (your doctor will know this)

• if there is a decreased volume of circulating blood in the body (hypovolaemia)
• if you have a serious irregular heart beat
• if you suffer from heart problems such as recent heart attack (within 30 days), swelling or tear in the wall of the blood vessel (artery) carrying blood out of the heart (aorta), insufficient blood flow to the heart or uncontrolled high blood pressure, swelling of the aorta- main artery of the body (aortic aneurysm)
• if you have rare, usually noncancerous tumor that develops in the center of an adrenal gland- glands that produce a wide variety of hormones (pheochromocytoma)
• if you have electrolyte imbalance (imbalance of certain salts in the blood like sodium, potassium and calcium) and severe anaemia (iron deficiency)
• if you have severe pain in the chest (angina).

Warnings and precautions:
Talk to your doctor or nurse before you are given Dobutamine Concentrate if
• you have recently had a heart attack
• you suffer from any type of heart disease
• you have any kidney disease
• you have low blood pressure along with heart problems
• you have suffered from significant blood and/or fluid losses in your body
• you suffer from a condition resulting in increased resistance of muscle to passive stretching (hypertonia)
• you have diabetes
• you suffer from asthma
• you have any condition that would make exercise dangerous for you
• you have impaired liver function
• you suffer from condition in which there is too much thyroid hormone in the body (hyperthyroidism).

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 if you are taking or have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking any of the following:
• drugs used as anaesthetics such as halothane, cyclopropane and other halogenated anaesthetics
• use of beta-blockers (medicines used to relieve certain heart conditions, anxiety and migraine e.g. propranolol and metoprolol used for angina, or high blood pressure or to regulate the rhythm of the heart)
• use of beta-blockers with alpha-blocking effects (medicine used to treat heart failure and high blood pressure e.g. carvedilol)
• entacapone (a medicine to treat Parkinson’s Disease)
• monoamine oxidase inhibitors (Treatments for depression)
• ACE-inhibitors, e.g. captopril (for high blood pressure or heart failure)
• antipsychotics (Treatments for mental illness)

• oxytocin (used in labour)
• peripheral vasoconstrictor agents such as noradrenaline
• peripheral vasodilators (e.g. nitrates, sodium nitroprusside)
• ergotamine or methysergide (Treatments for migraine)
• dipyridamole (A blood thinner)
• theophylline (A treatment for asthma)
• doxapram (For breathing problems)
• atropine sulphate (for inflammation of the iris of the eye or for eye examinations).

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 for advice before taking this medicine.

As with all drugs, this medicine should only be given in pregnancy and when breast feeding if absolutely necessary.

Driving and using machines:
You should not drive or use machinery if you are affected by the administration of Dobutamine Concentrate.

Dobutamine Concentrate contains sodium and sodium metabisulphite:

This medicine contains 1 mg sodium (main component of cooking/table salt) in each 20 ml ampoule. This is equivalent to 0.05 % of the recommended maximum daily dietary intake of sodium for an adult.

Dobutamine Concentrate contains the preservative sodium metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How you will be given Dobutamine Concentrate

This injection will be administered under the supervision of a doctor.
The solution will be diluted before administration and will then be given by infusion (as a drip through a needle or tube) into a vein.

Your doctor will decide on the most suitable dose for you. Your doctor will adjust the rate of administration and duration of infusion depending on your response as determined by your heart rate, blood pressure, urine flow and, where possible, measurements of heart output which will be monitored during administration of dobutamine. The dosage will be gradually reduced towards the end of treatment.

Use in Children:
For all paediatric age groups (neonates to 18 years) an initial dose of 5 micrograms/kg/minute, adjusted according to clinical response to 2 – 20 micrograms/kg/minute is recommended. Occasionally, a dose as low as 0.5-1.0 micrograms/kg/minute will produce a response. The required dose for children should be titrated in order to allow for the supposedly smaller “therapeutic width” in children.

If you are given more Dobutamine Concentrate than you should
As Dobutamine Concentrate 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 medicine, tell your doctor. The likely signs of an overdose are the occurrence of side-effects as listed below. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side-effects, although not everybody gets them. These effects are generally dose related.

All medicines can cause allergic reactions although serious allergic reactions are very rare.

If you experience any of the following side effects after you have been given this medicine, tell your doctor or nurse immediately.

- **Any sudden wheeziness, difficulty in breathing, swelling of the eye lids, face or lips, rash or itching (especially of your whole body), fever.**
- **A high concentration of eosinophils granulocytes in blood eosinophilia**
- **Severe chest pain (angina pectoris)**
- **Severe life-threatening asthmatic episodes may be due to sulphite sensitivity**
- **A temporary, sudden contraction in one location of heart muscles (arteriospasm coronary)**
- **If you experience fatal cardiac rupture during dobutamine stress testing**
- **If there is abnormal changes in electrocardiogram or heart rhythm (atrial fibrillation and ventricular fibrillation)**
- **If there is obstruction in the outflow of blood from heart, reduced blood supply to the heart muscle (myocardial ischaemia) or inflammation of the heart muscle (eosinophilic myocarditis)**
- **Heart attack (myocardial infarction)**

The following side-effects have been reported:

Very common: may affect more than 1 in 10 people

• increased heart rate
• irregular heartbeats (palpitations)
• too fast or too slow heartbeat (arrhythmia)
• fast heart rhythm that originates in one of the ventricles of the heart (ventricular tachycardia)
• extra heartbeat arising from upper chamber of heart (ectopic atrial beats)
• narrowing of the blood vessels of the heart (arteriospasm coronary)
• chest pain

Common: may affect up to 1 in 10 people

• headache
• rise in blood pressure; if blood pressure rises markedly, it indicates overdose
• non-specific chest pain
• feeling sick
• asthma.

Uncommon: may affect up to 1 in 100 people

• a fall in blood pressure below normal
• for patients on treatment with beta-blockers (drugs to treat high blood pressure), slight narrowing of blood vessels may be observed due to contraction of its walls.

Rare: may affect up to 1 in 1,000 people

• reactions at the site of intravenous infusion including Phlebitis (formation of blood clots) and local inflammatory changes.

Very rare: may affect up to 1 in 10,000 people
• low blood levels of potassium
• involuntary twitching of muscle (myoclonus) has been reported in patients with severe kidney failure receiving dobutamine.
• skin cell injury and cell death at the site of injection.
Not known: frequency cannot be estimated from the available data
• increased frequency of urination with inability to control the urge for passing urine.
• problems with your heart muscle (stress cardiomyopathy also known as Takotsubo syndrome) that present with chest pain, shortness of breath, dizziness, fainting, irregular heartbeat when dobutamine is used for stress echocardiography test

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie;
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dobutamine Concentrate

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 and ampoule label after 'Exp'. The expiry date refers to the last day of that month.
Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.
For single use only.
The solution must be diluted before use. Do not dilute with alkaline solutions. If diluted solution is not required immediately it may be stored for up to 24 hours at 2-8°C in a refrigerator.
If only part used, discard the remaining solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dobutamine Concentrate contains
The active substance is dobutamine (as hydrochloride). Each 20ml sterile concentrate for solution for infusion contains dobutamine hydrochloride equivalent to 250mg dobutamine.

The other ingredients are sodium metabisulphite (E223), hydrochloric acid and sodium hydroxide in water for injections.

What Dobutamine Concentrate looks like and contents of pack
Dobutamine Concentrate is a clear, colourless or almost colourless sterile concentrate for solution for infusion. Each 20ml contains dobutamine hydrochloride equivalent to 250mg dobutamine (Each 1ml contains dobutamine hydrochloride equivalent to 12.5mg dobutamine).
Pack sizes: 5 ampoules may be packaged together in cardboard cartons.

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