Package leaflet: Information for the user
Dobutamine 12.5 mg/ml Concentrate for solution for infusion
Dobutamine

The name of your medicine is Dobutamine 12.5 mg/ml Concentrate for solution for infusion, which will be referred to as Dobutamine throughout this leaflet.

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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. 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 contains the active ingredient dobutamine, which belongs to a group of medicines called beta receptor agonists (heart stimulants).
Dobutamine is used to stimulate the heart in adults who have heart failure caused by a heart attack, open-heart surgery and heart disease.
Dobutamine can also be used to for testing the heart when exercise testing is not possible.

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 use Dobutamine**
You should not be given Dobutamine if:
- You are allergic (hypersensitive) or might be allergic to dobutamine, sodium metabisulphite, sulphites, or any of the other ingredients of Dobutamine (see list of ingredients in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- You have an obstruction that interferes with blood flow out of your heart (your doctor will know this)
- You have a low blood volume that has not been corrected (your doctor will know this)
- You have an uncontrolled arrhythmia (heart rhythm)
- You suffer from high blood pressure due to a tumour near the kidney (Phaeocromocytoma).

You will also not be given Dobutamine to test your heart if:
- You have unstable (uncontrolled) angina
- You have uncontrolled high blood pressure
- You have an electrolyte (salt) imbalance
- You have severe anaemia (low red blood cells)
- You have suffered a heart attack within the last 30 days
- You have suffered an aortic dissection (bleeding caused by a tear in the wall of the aorta, the

major blood vessel that feeds blood to the body)
- You have suffered an aortic aneurysm (a weakened and bulging area in the aorta, the major blood vessel that feeds blood to the body)

Warnings and precautions
Take special care with Dobutamine and tell your doctor if you have any of the following conditions:
- Any heart disorder
- A liver or kidney disorder
- Hyperthyroidism (over-active thyroid)
- Severe hypotension (low blood pressure)
- A tumour of the adrenal gland
- Asthma
- A condition in which the concentration of potassium in the blood is low (Reduction in serum potassium concentration and hypokalaemia)
- Diabetes mellitus
- Hypovolaemia (dehydration)

Other medicines and Dobutamine
You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Dobutamine:
- Monoamine oxidase inhibitors (treatments for depression)
- Ergotamine or methysergine (treatments for migraine)
- Beta-adrenergic blockers such as propranolol or metoprolol
- Alpha-adrenergic blockers (for high blood pressure or enlarged prostate gland)
- Dipyridamole (a blood thinner)
- General anaesthetics
- Theophylline (a treatment for asthma)
- ACE-inhibitors, e.g. captopril (for high blood pressure or heart failure)
- Entacapone (a treatment for Parkinson's disease)
- Antipsychotics (treatments for mental illness)
- Doxapram (for breathing problems)
- Oxytocin (used in labour)
- Atropine sulphate (for inflammation of the iris of the eye or for eye examinations)
- Peripheral vasoconstrictor agents such as noradrenaline
- Peripheral vasodilators (e.g. nitrates, sodium nitroprusside)

It may still be all right for you to be given Dobutamine and your doctor will be able to decide what is suitable for you.
Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription.

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.

Pregnancy and breast-feeding

You will not be given Dobutamine if you are pregnant or breast-feeding unless your doctor thinks it is necessary.

Driving and using machines

Dobutamine have no effect on your ability to drive or use machinery.
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.
Dobutamine contains sodium metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How you will be given Dobutamine
You will be given Dobutamine in hospital by a doctor or nurse. Dobutamine is diluted and infused into a vein.
Dosage for stimulation of the heart
Adults and the elderly:
The usual dose is 2.5 to 10 micrograms/kg (body weight)/min, which is adjusted according to the heart rate, blood pressure, heart output and urine output. Doses up to 40 micrograms/kg/min may occasionally be required.

Dosage for stress testing of the heart
Adults:
The recommended dosage is an incremental increase from 5 to maximum 40 micrograms/kg/minute.
Elderly:
The recommended dosage is an incremental increase from 5 to maximum 20 micrograms/kg/minute.
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 receive more Dobutamine than you should

Your infusion will be stopped and you will be monitored closely. Your doctor will know the correct amount to give you.

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.

Very Common (affects more than 1 user in 10)

- Increased heart rate
- Palpitations
- Severe chest pain
- Irregular heartbeats
- Arrhythmia (too fast or too slow heartbeat)
- Ventricular tachycardia (fast heart rhythm that originates in one of the ventricles of the heart)
- Coronary artery spasm (temporary, sudden contraction in one location of heart muscles)
- Electrocardiogram ST segment elevation

Common (affects 1 to 10 users in 100)

- Hypersensitivity reactions including rash
- Fever
- Eosinophilia (high concentration of eosinophils granulocytes in blood)
- Bronchospasm (sudden constriction of the muscles in the walls of the bronchioles)
- Headache
- Hypertension
- Marked increase in systolic blood pressure indicates overdose
- Non-specific chest pain
- Shortness of breath
- Asthma
- Nausea

Uncommon (affects 1 to 10 users in 1,000)

- Atrial fibrillation (abnormal heart rhythm involves the two upper chambers-atria),
- Ventricular fibrillation (uncoordinated contraction of the cardiac muscle of the ventricles)
- Left ventricular outflow tract obstruction.
- Hypotension
- Slight vasoconstriction, especially in patients with pre-treated with β-blockers

Rare (affects 1 to 10 users in 10,000)

- Phlebitis (formation of blood clots)
- Local inflammatory changes
- Anaphylactic reactions (severe hypersensitivity allergic reaction)
- Severe life-threatening asthmatic episodes may be due to sulphite sensitivity

Very rare (affects less than 1 user in 10,000)

- As with other catecholamines, decreases in serum potassium concentrations have occurred.
- Myoclonus (involuntary twitching of muscle) has been reported in patients with severe renal failure receiving Dobutamine.
- Myocardial ischaemia (reduced blood supply to the heart muscle)
- Myocardial infarction (heart attack)
- Eosinophilic myocarditis (inflammation of the heart muscle)
- Fatal cardiac rupture during dobutamine stress testing
- Cutaneous necrosis

Unknown (cannot be estimated from the available data)

- Urinary urgency

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 any side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard.

Ireland
Pharmacovigilance Section
Irish Medicine Board, Kevin O'Malley House, Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971, Fax: +353 1 6762517
Website:www.imb.ie,
e-mail:imbpharmacovigilance@imb.ie

5. How to store Dobutamine
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 ampoule and the outer carton after "EXP". The expiry date refers to the last day of that month.
Do not store above 25°C. Discard any unused product.
Dobutamine Concentrate should be diluted before use and administered by IV infusion only. The final concentrations generally used for perfusion are 250 micrograms/ml, 500 micrograms/ml or 1000 micrograms/ml.
The following sterile solutions for IV infusion may be used for the dilution of dobutamine before use: sodium chloride solution 0.9% (9 mg/ml), glucose solution 5% (50 mg/ml), dextrose solution 5% (50 mg/ml), or Ringer lactate solution.

Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C. From a microbiological point of view the prepared infusion should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours at 2°C - 8°C unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions.

Diluted solutions of dobutamine hydrochloride may have a pink discolouration. This discolouration, which will increase with time, results from a slight oxidation of the drug. However, there is no significant loss of drug potency within the recommended maximum in-use storage time of 24 hours at 2°C - 8°C.

Do not use this medicine if you notice visible signs of deterioration or visible particles in the product.
Your doctor or pharmacist is responsible for the correct storage, use and disposal of Dobutamine.

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 protect the environment.

6. Contents of the pack and other information

What Dobutamine contains:
The active substance is dobutamine.

Each 1 ml contains 12.5 mg of dobutamine (as 14.01mg dobutamine hydrochloride).
Each 20 ml ampoule contains 250 mg of dobutamine (as 280.2 mg dobutamine hydrochloride).

The other ingredients are:
Sodium metabisulphite (E223), Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment) and Water for Injections

What Dobutamine looks like and contents of the pack
Dobutamine comes in 20 ml clear glass ampoule (type I), with a pack size of 5 and 1 ampoules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
United Kingdom:
Baxter Healthcare Limited
Caxton Way
Thetford, Norfolk IP24 3SE, United Kingdom

Ireland:
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht, Netherlands

Manufacturer
Peckforton Pharmaceuticals Limited

Crewe Hall, Golden Gate Lodge, Crewe, Cheshire, CW1 6UL

This medicinal product is authorised in the Member States of the EEA under the following names:

Estonia	Dobutamine Claris
France	Dobutamine Claris 12.5 mg/ml Concentrate for Solution for Infusion
Ireland	Dobutamine 12.5 mg/ml Concentrate for Solution for Infusion
Italy	Dobutamina Claris 12,5 mg/ml concentrato per soluzione per infusione
Latvia	Dobutamine Claris 12.5 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Dobutamine Claris 12,5 mg/ml koncentratas infuziniam tirpalui
Netherlands	Dobutamine Claris 12,5 mg/ml Concentraat voor oplossing voor infusie
Portugal	Dobutamina Claris 12,5 mg/ml Concentrado para solucao para perfusao
UK	Dobutamine 12.5 mg/ml Concentrate for Solution for Infusion

This leaflet was last revised in MM/YYYY

The following information is intended for healthcare professionals only:

Dobutamine Concentrate should be diluted before use and administered by IV infusion only through an intravenous needle or catheter. Due to its short half-life dobutamine should be administered as a continuous intravenous infusion. High concentrations of dobutamine should only be given with an infusion pump to ensure accurate dosage or other suitable apparatus.

The following sterile solutions for IV infusion may be used for the dilution of dobutamine before use: sodium chloride solution 0.9% (9 mg/ml), glucose solution 5% (50 mg/ml), dextrose solution 5% (50 mg/ml), or Ringer lactate solution.

Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C. From a microbiological point of view, the prepared infusion should be used immediately. If not used immediately, to keep in storage conditions prior to use is the responsibility of the user and should not be longer than 24 hours at 2°C - 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions".

Any unused product or waste material should be disposed of in accordance with local requirements.