

**Dobutamine 5 mg/ml solution for infusion**

**Read all of this leaflet carefully before you are given this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Dobutamine is and what it is used for
2. Before you are given Dobutamine
3. How Dobutamine is given
4. Possible side effects
5. How to store Dobutamine
6. Further information

**1. WHAT DOBUTAMINE IS AND WHAT IT IS USED FOR**

Dobutamine belongs to a group of medicines called catecholamines. It helps your heart to work more effectively. It works by strengthening the pumping action of the heart, increasing the amount of blood flow in the body and by expanding your veins and arteries.

**Dobutamine is used:**

- to treat heart failure (cardiac decompensation) if the heart is not beating strongly enough (depressed contractility),
- in heart failure where there is severe low blood pressure (hypotension),
- to detect poor blood supply to the heart (cardiac stress testing).

**2. BEFORE YOU ARE GIVEN DOBUTAMINE**

**You should not be given Dobutamine if**

- you are **allergic** (hypersensitive) to **Dobutamine** or **any of the other ingredients** (see list of ingredients in section 6). An allergic reaction may include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. You may know this from earlier experience.
- there is a **narrowing in your heart or blood vessels that prevents the heart from filling or ejecting blood properly** (your doctor will know this).
- there is a **lack of adequate circulatory filling** (hypovolaemia).

If you have certain heart or blood vessel disorders, Dobutamine should not be used to detect poor blood supply to your heart.

**Take special care with Dobutamine**

Tell your doctor if you have any of the following conditions:

- asthma and you have been told that you are allergic to sulphites,
- severe coronary heart disease,
- acute (sudden) heart failure.

**Using other medicines**

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines you can get without a prescription. This is especially important with the following medicines as they may interact with your Dobutamine:

- beta blockers (treatment of high blood pressure and irregular heart rhythms),



**The following information is intended for medical or healthcare professionals only:**

**PREPARATION GUIDE FOR:**

Dobutamine 5 mg/ml solution for infusion

Please refer to the Summary of Product Characteristics for full prescribing and other information.

**1. NATURE AND CONTENT OF CONTAINER**

1 ml solution contains 5 mg dobutamine.

Dobutamine is supplied in 50 ml clear glass ampoules or vials. It is available in original packages containing 1, 5 or 10 ampoules and packs containing 1, 5, 10 or 20 vials.

**2. POSOLOGY AND METHOD OF ADMINISTRATION**

When used for detection of myocardial ischaemia and of viable myocardium within the scope of an echocardiographic examination (dobutamine stress echocardiography), dobutamine may only be administered by a physician with sufficient experience in conducting cardiology stress tests. Continuous monitoring of all wall areas via echocardiography, and ECG as well as control of blood pressure is necessary.

Monitoring devices as well as emergency medicines must be available (e.g. defibrillator, I.V. beta-blockers, nitrates, etc.) and staff trained in the resuscitation procedure must be present.

The required rate of infusion depends on the patient's response to therapy and the adverse reactions experienced.

The dose of dobutamine should be gradually reduced when discontinuing therapy.

Any unused solution should be discarded.

**Dosage**

Dosage in adults:

According to experience, the majority of patients respond to doses of 2.5-10 µg dobutamine/kg/min. In individual cases, doses up to 40 µg dobutamine/kg/min have been administered.

Dosage in children:

- alpha blockers (treatment of high blood pressure and prostate enlargement),
- vasodilators (expanding blood vessels, used to treat an angina attack or severe heart failure),
- antidiabetics (treatment of diabetes),
- ACE inhibitors (treatment of high blood pressure and heart failure),
- dopamine (used to increase heart rate and blood pressure),
- inhaled anaesthetics.

It may still be alright for you to receive Dobutamine and your doctor will be able to decide what is suitable for you.

**Children**

Caution is advised in giving high doses of Dobutamine to children. Your doctor will adjust the required dose for your child carefully.

**Pregnancy and breast-feeding**

Dobutamine should not be given to pregnant women unless medically justified. It is recommended that you stop breast-feeding during your treatment with Dobutamine. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

If you have any concerns ask your doctor or pharmacist.

**Important information about some of the ingredients of Dobutamine**

Dobutamine contains **sodium metabisulphite** (E 223), which may rarely cause allergic reactions (hypersensitivity) and asthma-like symptoms (bronchospasm).

This medicinal product contains 3.05 mg **sodium** per 1 ml. This should be taken into consideration by patients on a controlled sodium diet.

**3. HOW DOBUTAMINE IS GIVEN**

Dobutamine will be given to you by specifically trained health care professionals and emergency equipment will be available.

**Dosage**

The required rate of infusion depends on your response to therapy and any side effects. Your doctor will decide the dose of Dobutamine you will be given and will adjust the flow rate and duration of your infusion.

Dosage in adults:

Most patients respond to doses of 2.5-10 micrograms of Dobutamine per kg body weight per minute. Doses up to 40 micrograms of Dobutamine per kg body weight per minute have been given.

Dosage in children:

Doses of 1 to 15 micrograms Dobutamine per kg body weight per minute have been given.

Doses of 1 to 15 µg dobutamine/kg/min have been administered. The minimum effective dosage for children is likely to be higher than that for adults. Caution should be taken when administering high doses, because the maximum tolerated dosage for children is lower than that for adults. Most adverse reactions (tachycardia in particular) are observed when the dosage is 7.5 µg dobutamine/kg/min or above.

The required dose for children should be titrated in order to allow for the narrower "therapeutic window" in children.

**Tables, showing infusion rates with different initial concentrations for various dosages:**

Intravenous infusion of Dobutamine is also possible after dilution with compatible infusion solutions such as: 5% glucose solution, 0.9% sodium chloride or 0.45% sodium chloride in 5% glucose solution. Infusion solutions should be prepared immediately before use.

Due to its short half-life, dobutamine must be administered as a continuous intravenous infusion.

One ampoule (or vial) Dobutamine 5 mg/ml (250 mg in 50 ml) diluted to a solution volume of 500 ml (final concentration 0.5 mg/ml)

Dosage range		Specifications in ml/h* (drops/min)		
		Patient's weight		
		50 kg	70 kg	90 kg
Low 2.5 µg/kg /min	ml/h (drops /min)	15 (5)	21 (7)	27 (9)
	ml/h (drops /min)	30 (10)	42 (14)	54 (18)
Medium 5 µg/kg /min	ml/h (drops /min)	60 (20)	84 (28)	108 (36)
	ml/h (drops /min)	60 (20)	84 (28)	108 (36)

\* For double concentration, i.e. 500 mg dobutamine added to 500 ml, or 250 mg added to 250 ml solution volume, infusion rates must be halved.

#### 4. POSSIBLE SIDE EFFECTS

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

**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)
- headache
- asthma-like symptoms (bronchospasm)
- shortness of breath
- increase in white blood cells (eosinophilia)
- inhibition of blood clot formation
- increased desire to urinate (at high doses)
- feeling sick (nausea)
- 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)
- restlessness
- pins and needles (paraesthesia)
- tremor
- feelings of heat and anxiety
- muscle cramp (myoclonic spasm)

Not known (cannot be estimated from the available data)

- chest pain caused by stress (stress cardiomyopathy)

**If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

#### 5. HOW TO STORE DOBUTAMINE

- Your doctor or pharmacist is responsible for storing Dobutamine. They are also responsible for disposing of any unused Dobutamine correctly.
- Keep out of the reach and sight of children.
- Do not use Dobutamine after the expiry date (EXP:) printed on the pack. The expiry date refers to the last day of that month.
- Do not use Dobutamine if you notice the solution is not clear and free of particles or if the container is damaged.

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#### Dosage for syringe pumps

One ampoule (or vial) Dobutamine 5 mg/ml (250 mg in 50 ml) undiluted (final concentration 5 mg/ml)

Dosage range		Specifications in ml/h (ml/min)		
		Patient's weight		
		50 kg	70 kg	90 kg
Low 2.5 µg/kg/min	ml/h (ml/min)	1.5 (0.025)	2.1 (0.035)	2.7 (0.045)
Medium 5 µg/kg/min	ml/h (ml/min)	3.0 (0.05)	4.2 (0.07)	5.4 (0.09)
High 10 µg/kg/min	ml/h (ml/min)	6.0 (0.10)	8.4 (0.14)	10.8 (0.18)

The chosen syringe pump must be suitable for the volume and rate of administration.

#### Precautions

Dobutamine must not be used in case of:

- known hypersensitivity to dobutamine or to any of the excipients,
- mechanical obstruction of ventricular filling and/or of outflow, such as pericardial tamponade, constrictive pericarditis, hypertrophic obstructive cardiomyopathy, severe aortic stenosis,
- hypovolaemic conditions.

Dobutamine stress echocardiography

Dobutamine must not be used for detection of myocardial ischaemia and of viable myocardium in case of:

- recent myocardial infarction (within the last 30 days),
- unstable angina pectoris,
- stenosis of the main left coronary artery,
- haemodynamically significant outflow obstruction of the left ventricle including hypertrophic obstructive cardiomyopathy,
- haemodynamically significant cardiac valvular defect,
- severe heart failure (NYHA III or IV),

- Keep the ampoules/vials in the outer carton in order to protect from light.
- Do not store above 25°C. Do not refrigerate or freeze.

#### 6. FURTHER INFORMATION

##### What Dobutamine contains

The active substance is dobutamine hydrochloride.

1 ml solution contains 5 mg dobutamine.

Each 50 ml ampoule/vial Dobutamine contains dobutamine hydrochloride corresponding to 250 mg dobutamine.

The other ingredients are sodium metabisulphite (E 223), sodium chloride, hydrochloric acid and water for injections.

##### What Dobutamine looks like and the content of the pack

Dobutamine is a clear colourless or almost colourless solution for infusion.

Dobutamine is supplied in 50 ml clear glass ampoules or vials. It is available in original packages containing 1, 5 or 10 ampoules and packs containing 1, 5, 10 or 20 vials.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder

hameln pharma plus gmbh

Langes Feld 13

31789 Hameln

Germany

##### Manufacturer

hameln pharmaceuticals gmbh

Langes Feld 13

31789 Hameln

Germany

##### Distributor

hameln pharmaceuticals ltd

Gloucester

United Kingdom

**For any information about this medicine, please contact the Distributor.**

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

DE Dobutamin-hameln 5 mg/ml

NL Dobutamine-hameln 5 mg/ml i.v.

infusievloeistof, oplossing voor infusie

UK Dobutamine 5 mg/ml solution for infusion

**This leaflet was last revised in April 2011.**

- predisposition for or documented medical history of clinically significant or chronic arrhythmia, particularly recurrent persistent ventricular tachycardia,
- significant disturbance in conduction,
- acute pericarditis, myocarditis or endocarditis,
- aortic dissection,
- aortic aneurysm,
- poor sonographic imaging conditions,
- inadequately treated / controlled arterial hypertension,
- obstruction of ventricular filling (constrictive pericarditis, pericardial tamponade),
- hypovolaemia,
- previous experience of hypersensitivity to dobutamine.

#### 3. INCOMPATIBILITIES

Dobutamine has proven to be incompatible with:

- beta blockers,
- primarily venous acting vasodilators (e.g. nitrates, sodium nitroprusside),
- ACE inhibitors (e.g. captopril),
- dopamine,
- thiamine (vitamin B1),
- inhaled anaesthetics,
- atropine.

Administering dobutamine to diabetic patients may cause increased insulin demand. Thus, in diabetic patients levels should be checked when starting dobutamine therapy, changing the rate of infusion and discontinuing the infusion. If necessary the insulin dose must be adjusted as required.

#### 4. STORAGE

Do not store above 25°C. Keep the ampoules/vials in the outer carton in order to protect from light.

Do not refrigerate or freeze.