

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 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.

What is in this leaflet

1. What Dobutamine is and what it is used for
2. What you need to know before you use Dobutamine
3. How to use Dobutamine
4. Possible side effects
5. How to store Dobutamine
6. Contents of the pack and other 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).

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

Do not use 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.

Warnings and precautions

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

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

Children

Increases 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)



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 and 10 ampoules and packs containing 1, 5, 10 and 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 paediatric patients:

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.

There is reason to believe that the minimum effective dosage for children is higher than for adults. Caution should be taken in

seems to be more often observed in adult patients than in small children. Accordingly, the use of Dobutamine in children should be monitored closely.

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

Other medicines and Dobutamine

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),
- 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 increasing heart rate and blood pressure),
- inhaled anaesthetics.

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

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.

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

Dobutamine contains sodium

This medicinal product contains less than 1mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.

3. HOW TO USE DOBUTAMINE

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

applying high doses, because there is also reason to believe that the maximum tolerated dosage for children is lower than the one for adults. Most adverse reactions (tachycardia in particular) are observed when dosage was higher than/equal to 7.5 micrograms/kg/minute but reducing or termination of the rate of dobutamine infusion is all that is required for rapid reversal of undesirable effects.

A great variability has been noted between paediatric patients in regard to both the plasma concentration necessary to initiate a hemodynamic response (threshold) and the rate of hemodynamic response to increasing plasma concentrations, which demonstrates that the required dose for children cannot be determined a priori and should be titrated in order to allow for the supposedly smaller "therapeutic width" in children.

Method of administration

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.

Paediatric patients: For continuous intravenous infusion using an infusion pump, dilute to a concentration of 0.5 to 1 mg/mL (max 5mg/mL if fluid restricted) with Glucose 5% or Sodium Chloride 0.9%. Infuse higher concentration solutions through central venous catheter only. Dobutamine intravenous infusion is incompatible with bicarbonate and other strong alkaline solutions.

Neonatal intensive care: Dilute 30 mg/kg body weight to a final volume of 50 mL of infusion fluid. An intravenous infusion rate of 0.5 mL/hour provides a dose of 5 micrograms/kg/minute.

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

One ampoule (or vial) Dobutamine 5 mg/ml (250 mg/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	15	21
2.5 µg/kg/min	ml/h (drops/min)	(5)	(7)	(9)

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:

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.

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)

- coronary artery disease by stress (stress cardiomyopathy)

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. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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 this medicine out of the sight and reach 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.
- Keep the ampoules/vials in the outer carton in order to protect from light.
- Do not refrigerate or freeze.

6. CONTENTS OF THE PACK AND OTHER 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 metabisulfite (E 223), sodium chloride, hydrochloric acid and water for injections.

What Dobutamine looks like and contents 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 and 10 ampoules and packs containing 1, 5, 10 and 20 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

hameln pharma gmbh
Inselstraße 1
31787 Hameln
Germany

Manufacturer

Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln
Germany

Distributor

hameln pharma 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

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Medium 5 µg/kg/min	ml/h (drops/min)	<u>30</u> (10)	<u>42</u> (14)	<u>54</u> (18)
High 10 µg/kg/min	ml/h (drops/min)	<u>60</u> (20)	<u>84</u> (28)	<u>108</u> (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.

Dosage for syringe pumps

One ampoule (or vial) Dobutamine 5 mg/ml (250 mg/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)	<u>1.5</u> (0.025)	<u>2.1</u> (0.035)	<u>2.7</u> (0.045)
Medium 5 µg/kg/min	ml/h (ml/min)	<u>3.0</u> (0.05)	<u>4.2</u> (0.07)	<u>5.4</u> (0.09)
High 10 µg/kg/min	ml/h (ml/min)	<u>6.0</u> (0.10)	<u>8.4</u> (0.14)	<u>10.8</u> (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),
- 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,
- in case of 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

Keep the ampoules/vials in the outer carton in order to protect from light.

Do not refrigerate or freeze.

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