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 a previous reaction.
- there is a narrowing in your heart or blood vessels that prevents the heart from filling or ejecting blood properly (cardiac hypertrophy).
- you are allergic (hypersensitive) to sodium metabisulfite (E 223), which may rarely cause allergic reactions (hypersensitivity) and asthma-like symptoms (bronchospasm).
- you are allergic (hypersensitive) to any of the other ingredients.

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

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 hypertensive effect (low blood pressure)

Dosage in adults:

- Dobutamine 5 mg/mL solution for infusion

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

PREPARATION GUIDE FOR:

Dobutamine 5 mg/mL solution for infusion

Dosage Range

 Dosage in adults:

According to experience, the majority of patients respond to dosages of 2.5-10 µg dobutamine/kg/min. In individual cases, dosages 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 4-8 µg dobutamine/kg/min, 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 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 required 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 window” in children.

Method of administration

Infravenous 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 infravenous infusion.

Paediatric patients: For continuous infravenous infusion using an infusion pump, dilute to a concentration of 0.5 to 1 mg/mL. 

Intravenous infusion rate

Dobutamine intravenous infusion is incompatible with bicitracine 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.

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

Driving and using machines

If you have any concerns ask your doctor or pharmacist.

Preparation and dilution

Dilute 30 mg/kg body weight to a final solution volume of 500 ml (final concentration 0.5 mg/ml). 

Dosage in adults:

Most patients respond to doses of 2.5-10 micrograms of Dobutamine you will be given and will adjust the flow rate and duration of your infusion.
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
  - blood pressure increase or decrease
  - narrowing of the blood vessels (vasoconstriction)
  - irregular heartbeat (palpitations)
  - ascites
  - 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)
  - uncontrollable 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
  - joint pain and needles (parasthesia)
  - tremor
  - feelings of heat and anxiety
  - muscle cramp (myasthenic 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 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 the packaging or contents 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 ampules and packs containing 1, 5, 10 and 20 vials.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
hamelin pharmasa plus gmbh
Langes Feld 13
31789 Hameln
Germany

**Manufacturer**
Siegfried Hameln GmbH
Langes Feld 13
31789 Hameln
Germany

**Distributor**
hamelin pharmasa plus 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.

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

This leaflet was last revised in August 2018.

**459935/18**

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**Do not refrigerate or freeze.**

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

Do not refrigerate or freeze.

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- 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, amyloidosis, 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),  
- hypoaemia,  
- 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.

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**STORAGE**
Keep the ampoules/vials in the outer carton in order to protect from light. Do not refrigerate or freeze.