PATIENT INFORMATION LEAFLET

DOBUTHAVER 250 mg/20 mL I.V. Ampoule Containing Concentrated Solution for Infusion Sterile
Administered intramuscularly or intravenously

- ***Active ingredient:*** Each 20 ml ampoule contains 280.2 mg dobutamine hydrochloride equivalent to 250 mg dobutamine as an active substance.
- ***Excipients:*** Sodium metabisulfite, water for injection and hydrochloric acid / sodium hydroxide for pH adjustment where necessary.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this patient information leaflet:

Headings are included.

1. What DOBUTHAVER is and what it is used for?

DOBUTHAVER Ampoule belongs to a group of drugs known as "inotropic (increases the contractile power of the heart)".
DOBUTHAVER is a very light yellow or colorless, clear, particulate-free solution and is supplied in 20 milliliter glass ampoules. Each 20-milliliter ampoule contains 280.2 mg dobutamine hydrochloride equivalent to 250 mg dobutamine as active ingredient.
DOBUTHAVER is used in the following situations:
Adults:
- In open heart surgeries
- In the treatment of heart diseases
- In the treatment of heart failure

- In cases of shock
- Used as an alternative to exercise in heart stress testing.

Children:

It is used as an inotropic (enhancing the contractile power of the heart) support in all pediatric age groups (newborns up to 18 years of age) in heart failure or heart failure that may develop due to a decrease in cardiac contraction after heart surgeries.

2. Before you are given DOBUTHAVER

DO NOT USE DOBUTHAVER in the following cases:

If;

- You have sensitivity or allergies to dobutamine, sodium metabisulfite or any of the ingredients of DOBUTHAVER
- You have high blood pressure due to the presence of a tumor in the adrenal glands (pheochromocytoma)
- You have certain heart or vascular disorders. Dobutamine should not be used to detect insufficient blood flow of the heart (heart stress test known as Dobutamine Stress Echocardiography).
- You have low blood volume (hypovolemia).

Use DOBUTHAVER CAREFULLY in the following cases:

If;

- You have recently had a heart attack
- You have a history of heart transplant
- You have an increased heart rate
- You have asthma
- You have unstable (unstable) angina (chest pain caused by narrowing / occlusion of the vessels feeding the heart)
- You have heart conditions
- You have high blood pressure
- You have any situation where exercising is dangerous for you

In children

Increases in heart rate and blood pressure are more frequent and more intense in children than in adults. It has been reported that the cardiovascular system in newborns is less sensitive to dobutamine and that hypotensive effect (lowering of blood pressure) occurs more frequently in adult patients than in young children. Therefore, use of dobutamine in children should be closely monitored.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

Use of DOBUTHAVER with food and drink

DOBUTHAVER is an intravenous drug; There is no interaction with food and drink in terms of administration method.

Pregnancy
Consult your doctor or pharmacist before using the medicine.
Do not use DOBUTHAVER during pregnancy unless it is considered particularly appropriate by your doctor.
If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before using the medicine.
If you are breastfeeding your baby, report this to your doctor. Do not use DOBUTHAVER during breastfeeding unless considered particularly appropriate by your doctor.

Driving and using machines
If you think you have a situation that will affect your ability to drive and use machines due to the application of DOBUTHAVER, do not drive and use machines.

Important information about some of the excipients contained in DOBUTHAVER content
DOBUTHAVER contains 4.8 mg of sodium metabisulfite per 20 milliliters. Sulfites may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).
Sodium: This medicinal product contains less than 0.05 mg of sodium per mL (23 mg). No sodium-related side effects are expected at this dose.

Using other medicines
As the following medicines may interact with dobutamine; special attention is required when using with DOBUTHAVER:

- Sensory loss agents (anesthetics);
- Beta blockers (drugs used to treat certain heart conditions, anxiety (anxiety) and migraine);
- Alpha blockers (drugs used to treat some heart conditions by relaxing the muscles in the blood vessels)
- ACE inhibitors (drugs used to treat blood pressure and reduce blood anxiety);
- Vasodilators (vasodilating drugs);
- Entacapone (a medicine used to treat Parkinson's disease);

If you are currently using or have recently used any prescribed or non-prescribed medicine, please inform your doctor or pharmacist.

3. How to use DOBUTHAVER

Instructions for use and dose/frequency of administration:
Your doctor will determine the dose of your pill depending on our disease and will administer it to you.

Route of administration and method:
It is administered intravenously with a suitable small tube (catheter) or injector. It is recommended for use with a calibrated electronic pump to control the flow rate of the solution.

Different age groups:

Use in children:
Your doctor will determine and apply the dose of the drug depending on the disease.

Use in the elderly:
Your doctor will determine and apply the dose of the drug depending on the disease.

Conditions of special use:
It has no special use.
If you have the impression that the effect of DOBUTHAVER is too strong or too weak, talk to your doctor or pharmacist.

If you use more DOBUTHAVER than you should:
DOBUTHAVER will always be administered to you by a healthcare professional. Therefore, it is unlikely to use an overdose, but if you think that your medication has been given too much, if you feel sick, feeling sick, anxiety, heart palpitations, headache, shortness of breath or chest pain, you should tell the healthcare professional administering the medicine.

If you use more DOBUTHAVER than you should, talk to a doctor or pharmacist.

If you forget to use DOBUTHAVER:
DOBUTHAVER will always be administered to you by a healthcare professional. Therefore doses are unlikely to be forgotten.
Do not take double doses to make up for forgotten doses.

If DOBUTHAVER treatment ends, effects may occur:
The drug should not be stopped suddenly. The drug should be discontinued by gradually reducing the dose.

4. Possible side effects

Like all other medicines, DOBUTHAVER may cause side effects in patients with hypersensitivity to any component of the drug.
Before administering DOBUTHAVER to you, your doctor will examine your heart to determine whether you are suitable for the medicine.

The frequency of adverse events is reported using the following categories;

Very common : can be seen at least 1 out of 10 patients.
Common : can be seen less than one in 10 patients, but more than one in 100 patients.

Uncommon : can be seen less than one in 100 patients, but more than one in 1,000 patients.
Rare : can be seen less than one in 1.000 patients, but can be seen more than 10,000 patients in one.
Very rare : can be seen less than one in 10,000 patients.
Unknown : cannot be estimated from available data.

Very common side effects:

- Increased heart rate
- Chest pain
- Heart beat irregularities (arrhythmias)

Common side effects:

- Increase or decrease in blood pressure
- narrowing of the vessels (vasoconstriction)
- Headache
- Chest pain
- Palpitations
- Asthma-like symptoms (bronchospasm)
- Shortness of breath
- Nausea
- An increase in the number of eosinophils (a type of allergy cell) in the blood
- Inhibition (prevention) of blood clot formation
- Rash (exanthema)
- Increased urge to urinate (at high doses)
- Fever
- Inflammation of the veins at the injection site (phlebitis)

Uncommon side effects:

- Rapid contraction of the heart ventricle (ventricular tachycardia)
- Life-threatening heart beat (ventricular fibrillation)
- Heart attack (myocardial infarction)

Very rare side effects:

- Slow heart rate (bradycardia)
- Insufficient blood flow to the heart (myocardial ischemia)
- Potassium level in the blood below normal (hypokalaemia)
- Point-shaped subcutaneous hemorrhages (petechial bleeding)
- Heart conduction block
- Narrowing of the vessels that feed the heart (coronary vasospasm)
- Skin necrosis

Unknown:

- Stress chest pain (stress cardiomyopathy)
- Allergic reactions (hypersensitivity reactions), including rash, fever, increased number of eosinophils (a type of allergy cell) in the blood and asthma-like symptoms

(bronchospasm)
- Serious allergic reactions (anaphylactic reactions) and life-threatening asthma attacks (see section 2) due to sodium metabisulfite sensitivity.
- Sudden and short-term contraction of a muscle or muscle group (myoclonus) in patients with severe renal insufficiency.
- Abnormal heart function tests (electrocardiogram ST segment elevation)
- Inflammation of the heart muscle (eosinophilic myocarditis) in patients with heart transplant
- Heart block (narrowing in the left ventricular canal of the heart)
- Fatal heart rupture (rupture)
- Restlessness
- Feeling sick
- Numbness in the limbs (paranesthesia)
- Shivering
- Hot flashes and anxiety

If you think that you have any of the above side effects, this may be serious, inform your doctor, nurse or pharmacist.
If you experience any side effects that are not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store DOBUTHAVER

Keep DOBUTHAVER in places out of sight and reach of children and within the packaging.
Use in accordance with the expiry date.
Do not use DOBUTHAVER after the expiration date which is stated on the package.
Store at room temperature below 25 ° C, protect from light.
"Do not use DOBUTHAVER if you find that the solution is not clear and contains particles."
It must be diluted to a minimum of 50 mL before intravenous infusion.
Diluted solutions for intravenous use are stable for 24 hours when prepared under aseptic conditions and stored in a refrigerator.
Unused portion should be discarded.
Dobutamine hydrochloride solutions may turn pink over time. This color change is due to the slightly oxidization of the drug. However, the effect of the drug is not lost within the recommended storage period.

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