



PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

**NOREPINEPHRINE BITARTRATE
INJECTION USP
4 MG/2ML
TAJ PHARMA**

Norepinephrine bitartrate

Read all of this leaflet carefully before you start taking 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 signs 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).

Please note that the leaflet also contains information about other strengths, Norepinephrine bitartrate 4mg/2ml Injection

WHAT IS IN THIS LEAFLET

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

1. WHAT NOREPINEPHRINE BITARTRATE IS AND WHAT IT IS USED FOR

Norepinephrine bitartrate for Solution for Infusion is used in an emergency to increase blood pressure to normal levels.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NOREPINEPHRINE BITARTRATE

Do not take Norepinephrine bitartrate

- if you are allergic to Norepinephrine bitartrate preparations or to any of the other ingredients of this medicine (listed in section 6). Tell your doctor if any of the above applies to you before this medicine is used

Warnings and precautions

Talk to your doctor or pharmacist before taking Norepinephrine bitartrate if you have:

- diabetes
- high blood pressure
- an over-active thyroid

- low levels of oxygen in the blood
- high levels of carbon dioxide in the blood
- clots or obstructions in the blood vessels supplying the heart, intestines, or other parts of the
- body low blood pressure following a heart attack
- a type of angina (chest pain) called Prinzmetal's angina.
- are elderly

Other medicines and Norepinephrine bitartrate

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines.

A number of medicines are known to increase the toxic effects of Norepinephrine, such as:

- Monoamine oxidase inhibitors (antidepressants)
- tricyclic antidepressants
- linezolid (an antibiotic)
- anaesthetics (especially anaesthetic gases)
- adrenergic-serotonergic medicines, e.g. used in the treatment of asthma and heart conditions.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Norepinephrine bitartrate may harm the unborn baby. Your doctor will decide if you should be given Norepinephrine bitartrate.

Norepinephrine Concentrate contains sodium The 2 ml ampoule contains 6.7 mg sodium, and the 4 ml ampoule contains 13.3 mg sodium. Take into consideration if you are on a low-sodium diet.

3. HOW TO TAKE NOREPINEPHRINE BITARTRATE

Norepinephrine bitartrate will be given to you in hospital by a doctor or nurse. It is first diluted and then infused into a vein.

The recommended dose of Norepinephrine bitartrate will depend on your medical condition. The usual dose is between 0.4 and 0.8 mg per hour. Your doctor will determine the correct dose for you. After the initial dose your doctor will assess your response and adjust the dose accordingly.

If you are given more or forget to take Norepinephrine bitartrate:

It is unlikely that you will receive too much or too little of this medicine, as this medicine will be given to you in hospital. However, talk to your doctor or nurse if you have any concerns. Symptoms of overdose are severe high blood pressure, slow heartbeat, violent headache, light sensitivity, pain in the chest, pale colour, intense sweating and vomiting.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately if you experience:

- sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), feeling that you are going to faint.
- pain and/or swelling at the injection site

Tell your doctor as soon as possible if you experience

- slow heart rate
- abnormal heart rhythm
- breathing difficulties
- anxiety
- headaches
- cold extremities
- pain in the extremities

Your doctor will monitor your blood pressure and blood volume.

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.

5. HOW TO STORE NOREPINEPHRINE BITARTRATE

Keep this medicine out of the sight and reach of children

Do not store above 25°C

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that

month.

From a microbiological point of view, the product should be used immediately after dilution.

Do not use this medicine if the solution is brown in colour.

Do not throw away any medicines via wastewater. Ask your pharmacists how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND FURTHER INFORMATION

What Norepinephrine bitartrate contains
1 ampoule of 2 ml contains:

Norepinephrine bitartrate equivalent to
Norepinephrine.....4mg

when diluted as recommended, each ml contains 80 micrograms Norepinephrine bitartrate equivalent to 40 micrograms Norepinephrine base.

The other ingredients are:

- sodium chloride
- sodium hydroxide (for pH adjustment)
- hydrochloric acid (for pH adjustment)
- Water for Injections.

What Norepinephrine bitartrate looks like



and contents of the pack:

This medicinal product is presented as a concentrate for solution for infusion. The solution is a clear colourless or yellowish solution.

It may be supplied in packs of 5 x 2 ml ampoules or 5 x 4 ml ampoules.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00

p.m. EST

E-mail: tajgroup@tajpharma.com