

Package leaflet: Information for the user

Bupivacaine-Amneal 2.5 mg/ml Solution for injection

Bupivacaine-Amneal 5 mg/ml Solution for injection

Bupivacaine hydrochloride monohydrate

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bupivacaine-Amneal is and what it is used for
2. What you need to know before you are given Bupivacaine-Amneal
3. How to use Bupivacaine-Amneal
4. Possible side effects
5. How to store Bupivacaine-Amneal
6. Contents of the pack and other information

1. What Bupivacaine-Amneal is and what it is used for

Bupivacaine-Amneal contains a medicine called bupivacaine hydrochloride. It belongs to a group of medicines called amide-type local anaesthetics. It produces a loss of feeling or sensation that is confined to one part of the body.

Bupivacaine-Amneal is used to numb (anaesthetise) parts of the body. It is used to stop pain happening or to provide pain relief. It can be used to:

- Numb parts of the body during surgery in adults and children above 12 years.
- Relieve pain in adults, infants and children above 1 year of age.

2. What you need to know before you are given Bupivacaine-Amneal

Do not use Bupivacaine-Amneal:

- If you are allergic (hypersensitive) to bupivacaine hydrochloride monohydrate or local anaesthetics of the amide type or to any of the other ingredients in this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- To produce local anaesthesia by injecting it into a vein of a limb that has been isolated from the circulation by means of a tourniquet (a technique called intravenous regional anaesthesia or Bier's-block)
- If you are having obstetrical paracervical block (a type of anaesthesia given during labour).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using **Bupivacaine-Amneal**

- any liver disorder
- a blood infection (septicaemia)
- very low or very high blood pressure
- dehydration or any recent vomiting, diarrhoea or blood loss
- heart disease
- a tumour or an accumulation of fluid in the abdomen.
- pleural effusions (fluid in the lungs) and septicaemia (blood poisoning)
- in children less than 12 years as some injections of Bupivacaine-Amneal in order to numb parts of the body during surgery are not established in younger children. The use of Bupivacaine-Amneal is not established in children less than 1 year of age.

Other medicines and Bupivacaine-Amneal

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

Taking some medicines together can be harmful. Remember that the doctor at the hospital may not have been informed if you have recently begun a course of treatment for another illness. In particular tell your doctor if you are taking

- other local anaesthetics
- medicines to control your heartbeat (such as lidocaine, mexiletine, or amiodarone)
- clonidine (used to treat high blood pressure or migraine)
- ketamine (an anaesthetic)

Pregnancy and breast-feeding

You must not have an obstetrical paracervical block (a type of anaesthesia during labour) if you are receiving this medicine.

Bupivacaine may get into breast milk. If you are breast-feeding you should discuss options with your doctor.

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.

Driving and using machines

Do not drive or use any tools or machines because Bupivacaine may interfere with your ability to do so safely. Ask your doctor when it would be safe to resume these activities.

Bupivacaine-Amneal contains

This medicinal product contains 0.14 mmol (3.15 mg) sodium per ml. To be taken into consideration by patients on a controlled sodium diet.

3. How to use Bupivacaine-Amneal

This medicine will be given to you by your doctor who will have the necessary knowledge and experience in the technique of epidural anaesthesia.

This medicine is for single use only.

Dose

Your doctor will decide what dose is right for you. This will normally be between 15-150 mg of Bupivacaine hydrochloride monohydrate. The dose will depend on your size, your state of health, the part of the body that the medicine is injected into and what the medicine is being used for. Smaller doses are used for elderly people, young children and people who are unwell.

You may be given this medicine before minor or major surgery, or during childbirth. For minor surgery, the injection will usually be given near the part of the body to be operated on. The medicine will prevent pain and cause numbness which will gradually wear off once the procedure is over. For major surgery or childbirth, you may be given an injection in your back which will take a few minutes. This will prevent pain and cause numbness in the lower half of your body which usually lasts for 3 to 4 hours.

For most procedures, one dose is enough but more doses may be needed if the procedure takes a long time.

Route and method of administration

This medicine is for epidural use, intraarticular use, subcutaneous use or intramuscular use only. Epidural anaesthesia involves an injection into the spine that can cause both a loss of sensation (an anaesthetic) as well as pain relief (an analgesic) by blocking the transmission of pain signals through nerves in or near the spinal cord. It can be used as an anaesthetic, as a pain reliever (an analgesic) together with general anaesthesia, and for postoperative pain relief (analgesia) in procedures involving the lower limbs, perineum, pelvis, abdomen and thorax.

If you have been given more Bupivacaine-Amneal than you should

It is unlikely that you will be given too much Bupivacaine-Amneal as it will be administered by a medical professional. However, if you are concerned, contact your doctor or nurse immediately.

If you forget to take Bupivacaine-Amneal

If you think you have missed a dose, please tell your doctor or nurse.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

Serious side effects

If you develop any of the following side effects, contact your doctor immediately:

- Fits
- Heart attack - rare

The following side effects have also been reported:

Very Common (may affect more than 1 in 10 people)

Nausea (feeling sick), low blood pressure (your doctor can monitor this).

Common (may affect up to 1 in 10 people)

Slow heartbeat, pins and needles, dizziness, vomiting, not being able to urinate, and high blood pressure (your doctor can monitor this).

Uncommon (may affect up to 1 in 100 people)

Pins and needles around the mouth, numbness of the tongue, sensitivity to sound, visual disturbances, loss of consciousness, tremor, light-headedness, ringing in the ears, and speech disorder.

Rare (may affect up to 1 in 1,000 people)

Nerve disorders or injury, loss of movement, paralysis, double vision, and shallow breathing.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bupivacaine-Amneal

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the vial and the box after “EXP”. The expiry date refers to the last day of that month.

Store below 30°C. Do not refrigerate or freeze.

Shelf life after dilution:

Chemical and physical in use stability has been demonstrated for 36 hours at 25°C.

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

After first opening: to be used immediately.

Do not use this medicine if container is damaged. Only clear solutions practically free from particles should be used.

Any unused solution should be discarded.

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

6. Contents of the pack and other information

What Bupivacaine-Amneal contains

The active substance is bupivacaine hydrochloride monohydrate.

For Bupivacaine-Amneal 2.5mg/ml Solution for injection

Each ml contains 2.5 mg of Bupivacaine hydrochloride monohydrate

Each 10 ml glass vial contains 25 mg of bupivacaine hydrochloride monohydrate.

Each 20 ml glass vial contains 50 mg of bupivacaine hydrochloride monohydrate.

For Bupivacaine-Amneal 5 mg/ml Solution for injection

Each ml contains 5 mg of bupivacaine hydrochloride monohydrate

Each vial with 10 ml contains 50 mg of bupivacaine hydrochloride monohydrate.

Each vial with 20 ml contains 100 mg of bupivacaine hydrochloride monohydrate.

The other ingredients are sodium chloride, 0.4% sodium hydroxide, 0.85% hydrochloric acid and water for injections.

What Bupivacaine-Amneal looks like and content of the pack:

Bupivacaine-Amneal is a clear, colourless, aqueous, sterile solution for injection supplied in 10 ml and 20 ml glass vial.

Pack sizes:

5 X 10 ml solution for injection

1 X 20 ml solution for injection

Not all packs sizes may be marketed.

Marketing Authorization Holder:

Amneal Pharma Europe Limited

70 Sir John Rogerson's Quay

Dublin 2

Ireland

Manufacturer:

Pfizer Service Company BVBA

Hoge Wei 10, 1930, Zaventem

Belgium

Pfizer Amboise: Pfizer PGM, Zone Industrielle 29, route des Industries 37530 POCE-SUR-CISSE,
France

This leaflet was last revised in 11/2013.

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The following information is intended for healthcare professionals only:

Any unused solution should be adequately disposed of, in accordance with local requirements.

1. Administration

Solution for injection.

The medicinal product is for epidural use, intraarticular use, subcutaneous use or intramuscular use only.

The maximum dosage must be determined by evaluating the size and physical status of the patient and considering the usual rate of systemic absorption from a particular injection site. A single dose of up to 150 mg bupivacaine hydrochloride monohydrate can be used. Doses of up to 50 mg 2-hourly may subsequently be used. A total dose of up to 500 mg bupivacaine hydrochloride monohydrate over 24 hours, which does not include the initial bolus dose, can be used routinely. For young, elderly or debilitated patients, the doses should be reduced.

2. Handling Instructions

For single use only.

Bupivacaine is compatible when mixed with sodium chloride 9 mg/ml (0.9%) solution for injection, Ringer Lactate Solution and Sufentanil Citrate 50 µg/ml. However, this medicinal product must not be mixed with any other medicinal products.