

Package leaflet: Information for the user

Bupivacaine Baxter 2.5 mg/ml solution for injection Bupivacaine Baxter 5 mg/ml solution for injection

Bupivacaine hydrochloride

Read all of this leaflet carefully before you start using 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 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 Baxter is and what it is used for
2. What you need to know before you use Bupivacaine Baxter
3. How to use Bupivacaine Baxter
4. Possible side effects
5. How to store Bupivacaine Baxter
6. Contents of the pack and other information

1. What Bupivacaine Baxter is and what it is used for

Bupivacaine Baxter is a local anaesthetic. It belongs to a group of medicines called amide-type local anaesthetics. It works by blocking the transmission of pain signals through nerves in or near the spinal cord. It is used to numb or make parts of the body free from pain.

Bupivacaine Baxter can be used to:

- numb parts of the body during surgery in adults and adolescents above 12 years
- relieve of acute pain in adults, infants and children above 1 year of age

It is used for example in surgical operations and as relief of pain after an operation.

2. What you need to know before you use Bupivacaine Baxter

You should not be given Bupivacaine Baxter:

- if you are allergic to bupivacaine hydrochloride or local anaesthetics of the amide type or to any of the other ingredients of this medicine (listed in section 6).
- to numb an area by injecting Bupivacaine Baxter into a vein
- to produce epidural anaesthesia in case you have:
 - very low blood pressure or low blood volume
 - a disease in the central nervous system, e.g. meningitis, polio, tumours, increased pressure or bleedings into your brain
 - a disease in the backbone (e.g. spondylitis, tuberculosis, tumours, recent traumas), spinal stenosis (an abnormal narrowing of spaces in the backbone which causes pressure on the spinal cord and nerves)
 - blood-poisoning
 - problems with your spinal cord due to anaemia
 - an infection near to where the injection will be given
 - heart problems
 - problems with blood clotting or if you have been given medicines to reduce blood clotting (with the exception of medicines containing the substance heparin)

Warnings and precautions

Talk to your doctor or nurse before you are given Bupivacaine Baxter if you have any of the diseases or conditions below

- if you are elderly and
 - have any liver disorder
 - have any kidney disorder
 - are in a generally impaired condition
- very low or very high blood pressure
- heart disease

Children

Bupivacaine Baxter is not recommended in children less than 1 year and only recommended for limited indications in children under 12 years.

Other medicines and Bupivacaine Baxter

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 irregular heartbeat (such as dronedarone or amiodarone)

Pregnancy and breast-feeding

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

Depending on dose and method of administration Bupivacaine Baxter may affect your ability to drive and use machines. Ask your doctor or nurse when it could be safe to resume these activities.

Bupivacaine Baxter contains sodium

This medicine contains 3,15 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,16% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Bupivacaine Baxter

Bupivacaine Baxter will be given to you by your doctor by injection. It can be injected subcutaneously (under the skin), intramuscularly (into a muscle), intraarticularly (into a joint) or as an epidural injection (into your back).

Recommended dosage:

Your doctor will decide what doses is right for you. 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.

Use in children and adolescents

Depending on the type of required analgesia and on the age and weight of the patient, the dosage will be determined by the doctor.

If you are given more Bupivacaine Baxter than you should

Serious side effects from getting too much Bupivacaine Baxter are unlikely. They need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Bupivacaine Baxter are usually as follows:

- feeling dizzy or light-headed
- numbness of the lips and around the mouth.
- numbness of the tongue.
- hearing problems.
- problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you Bupivacaine Baxter as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Bupivacaine Baxter, tell your doctor immediately.

More serious side effects from being given too much Bupivacaine Baxter include twitching of your muscles, fits (seizures), and loss of consciousness.

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 the following rare side effect:

Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) (may affect up to 1 in 1,000 people).

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

- Fits (uncommon side effect, may affect up to 1 in 100 people)
- Heart attack (rare side effect, may affect up to 1 in 1,000 people)

The following side effects have also been reported:

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

- nausea (feeling sick)
- low blood pressure

Common (may affect up to 1 in 10 people)

- slow heartbeat
- pins and needles
- dizziness
- vomiting
- not being able to urinate
- high blood pressure

Uncommon (may affect up to 1 in 100 people)

- convulsions
- pins and needles around the mouth, numbness of the tongue
- sensitivity to sound, ringing in the ears
- visual disturbances
- loss of consciousness

- tremor
- light-headedness
- speech disorder

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

- nerve disorders or injury
- loss of movement, paralysis
- double vision
- shallow breathing
- a condition called arachnoiditis (inflammation of the membrane that surrounds the spinal cord). The signs include a stinging or burning pain in the lower back or legs and tingling, numbness or weakness in the legs.

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 any 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 Baxter

Keep this medicine 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 carton after “EXP”. The expiry date refers to the last day of the month.

Do not refrigerate or freeze.

After first opening: to be used immediately

Only clear solutions practically free from particles should be used. Do not use if container is damaged. Any unused solution should be discarded.

Do not throw away any medicines via wastewater or 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 Baxter contains

The active substance is bupivacaine hydrochloride.

For 2.5mg/ml

Each ml contains 2.5 mg of bupivacaine hydrochloride

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

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

For 5 mg/ml

Each ml contains 5 mg of bupivacaine hydrochloride

Each 10 ml glass vial contains 50 mg of bupivacaine hydrochloride.

Each 20 ml glass vial contains 100 mg of bupivacaine hydrochloride.

Other ingredients – Sodium chloride, sodium hydroxide, hydrochloric acid and water for injections.

What Bupivacaine Baxter looks like and contents of the pack

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

Pack sizes:

5 and 10 X 10 ml Solution for Injection

1, 5 and 10 X 20 ml Solution for Injection

Not all packs sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Bieffe Medital S.p.A

Via Nuova Provinciale

23034 Grossotto (SO) Italy

Baxter

Boulevard René Branquart, 80

7860 Lessines

Belgium

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<Detailed information on this medicine is available on the web site of {MA/Agency}>

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The following information is intended for healthcare professionals only:

1. Administration

Solution for injection.

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

Bupivacaine may precipitate if diluted with alkaline solutions and should not be diluted or co-administered with sodium bicarbonate injections. This medicinal product must not be mixed with other medicinal products.

For dosing instructions please refer to the SmPC section 4.2.

2. Handling Instructions

For single use only.

Only clear solutions practically free from particles should be used. Any unused solution should be discarded.

Do not use Bupivacaine Baxter after the expiry date as indicated on the carton after “EXP”. The expiry date refers to the last day of the month.

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

3. Storage information

Do not refrigerate or freeze.

After first opening: to be used immediately.