Baxter **Baxter Pharmaceuticals India Private Limited**

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Barcode Information:

Barcode Scan Report:

Packing: 10ml Tub. Vial	**Plant Location : Injectable**
Country: United Kingdom, Ireland	**Language : English**
Ref. Code Creation/Blockage Note:	**Artwork Control Key No.:**

"Controlled Copy" Holder (1) (2) (3) (4) (5)

Date: 15/02/24

Package Leaflet: Information for the User
Bupivacaine 2.5mg/ml Solution for Injection
Bupivacaine 5 mg/ml Solution for Injection
bupivacaine hydrochloride monohydrate

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 or pharmacist or nurse.
- If you get any side effects, talk to your doctor or 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 is and what it is used for

Bupivacaine contains the active substance Bupivacaine hydrochloride monohydrate.
It belongs to a group of medicines called local anaesthetics.

Bupivacaine 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 use Bupivacaine

Do not use Bupivacaine:
- If you are allergic to bupivacaine hydrochloride monohydrate, or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- If you have a skin infection near to where the injection will be given.

You must not be given this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before using Bupivacaine.

- If you have heart, liver or kidney problems. This is because your doctor may need to adjust the dose of Bupivacaine. Problems with your liver enzymes may occur, particularly if you have long-term treatment with this medicine.
- If you have epilepsy.
- If you have been told that you have decreased volume of blood (hypovolaemia).

Children
In children aged less than12 years as some injections of Bupivacaine in order to numb parts of the body during surgery are not established in younger children. The use of Bupivacaine is not established in children less than 1 year of age.
If you are not sure if any of the above apply to you, talk to your doctor or nurse before you are given this medicine.

Other medicines and Bupivacaine
Tell your doctor or pharmacist if you are taking have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Bupivacaine can affect the way some medicines work and some medicines can have an effect on Bupivacaine.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines used to treat an uneven heart beat (arrhythmia) such as lidocaine, mexiletine or amiodarone.

Your doctor needs to know about these medicines to be able to work out the correct dose of Bupivacaine for you

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 this medicine

Pregnancy
There are no or limited amount of data from the use of bupivacaine in pregnant women.

Breast-feeding
Bupivacaine enters the mother's milk, if you are breast-feeding you should discuss options with your doctor.

Fertility
There are no data on the effect of bupivacaine on human fertility.

Driving and using machines

Bupivacaine may make you feel sleepy and affect the speed of your reactions. After you have been given Bupivacaine, you should not drive or use tools or machines until the next day.

Bupivacaine Solution contains sodium
This medicinal product contains 3.15 mg/ml (0.14 mmol) sodium per dose. Your doctor will take this into account if you are on a sodium controlled diet.

3. How to use Bupivacaine

Bupivacaine will be given to you by your doctor. Your doctor will know the correct way to give you this medicine.

The dose that your doctor gives you will depend on the type of pain relief that you need and the part of your body that the medicine will be injected into. It will also depend on your body size, age, and physical condition. Usually one dose will last long enough but more doses may be given if the surgery takes a long time.

Bupivacaine will be given to you as an injection or infusion. The part of the body where you are injected will depend on why you are being given Bupivacaine. Your doctor will give you Bupivacaine in one of the following places:

- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (an injection around the spinal cord).

When Bupivacaine is injected into the body in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will slowly wear off when the medical procedure is over.

Use in children and adolescents
Depending on the type of required analgesia Bupivacaine is injected slowly either into the epidural space (part of the spine) or other parts of the body by a doctor experienced in paediatric anaesthetic techniques. Dosage depends on the age and weight of the patient and will be determined by the doctor.

If you use more Bupivacaine than you should
Serious side effects from getting too much Bupivacaine 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 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 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, **tell your doctor immediately.**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects have also been reported:

Severe allergic reactions (rare, may affect up to 1 in 1,000 people)
If you have a severe allergic reaction, **tell your doctor immediately.** The signs may include sudden onset of:
- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

Other possible side effects:

Very common (may affect more than 1 in 10 people)
- Low blood pressure. This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

Common (may affect up to 1 in 10 people)
- Being sick (vomiting).
- Feeling dizzy.

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 perineural 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. Experience to date indicates a single dose of up to 150 mg bupivacaine hydrochloride monohydrate. Doses of up to 50 mg 2-hourly may subsequently be used. A maximum dose of 2 mg/kg should not be exceeded in any four-hour period. For young, elderly or debilitated patients, these doses should be reduced.

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 Injection after the expiry date as indicated on the box after "EXP". The expiry date refers to the last day of that month.

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- Pins and needles.
- High blood pressure (hypertension).
- Slow heart beat.
- Problems passing water.

Uncommon (may affect up to 1 in 100 people)
- Feeling light-headed.
- Fits (seizures).
- Numbness of the tongue or around the mouth.
- Ringing in the ears or being sensitive to sound.
- Difficulty in speaking.
- Blurred sight or double vision.
- Loss of consciousness.
- Shaking (tremors).
- Twitching of your muscles.

Rare (may affect up to 1 in 1,000 people)
- Nerve damage that may cause changes in sensation or muscle weakness (neuropathy). This may include peripheral nerve damage.
- 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.
- Weak or paralysed legs.
- Uneven heart beat (arrhythmias). This could be life-threatening.
- Slowed or stopped breathing or stopped heart beat. This could be life-threatening.

Possible side effects seen with other local anaesthetics which might also be caused by Bupivacaine include:
- Damaged nerves. Rarely this may cause permanent problems.
- Blindness which is not permanent or problems with the muscles of the eyes that are long-lasting. This may happen with some injections given around the eyes.

Additional side effects in children and adolescents
Side effects in children are similar to those in adults.
Do not be concerned by this list of possible side effects. You may not get any of them.

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. You can also report any side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance
Website:www.hpra.ie,

5. How to store Bupivacaine

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 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
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 waste-water 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 contains
The active substance is bupivacaine hydrochloride monohydrate.

For 2.5mg/ml
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 5 mg/ml
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.

Other ingredients are Sodium Chloride, 0.4% Sodium hydroxide, 0.85% hydrochloric acid and Water for injections.

What Bupivacaine looks like and content of the pack:

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

Pack sizes:
5, 10 X 10 ml solution for injection
1, 5, 10 X 20 ml solution for injection

Not all packs sizes may be marketed.

Marketing Authorization Holder:
United Kingdom:
Baxter Healthcare Limited
Caxton way
Thetford
Norfolk
IP24 3SE

Ireland:
Baxter Holding B.V.
Kobaltweg 49,
3542CE Utrecht, Netherlands

XXXXXXXXXX

Manufacturer:

Bieffe Medital S.p.A.
Via Nuova Provinciale 23034
Grossotto (SO) Italy

Or

UAB Norameda
Meistru 8a, 02189,
Vilnius, Lithuania

This medicinal product is authorized in the Member States of the European Economic Area and in the United Kingdom(Northern Ireland) under the following names:

Germany	Bupivacain-Baxter 2,5 mg/ml Injektionslösung
	Bupivacain-Baxter 5 mg/ml Injektionslösung
Estonia	Bupivacaine Baxter 5 mg/ml süstelahus
Ireland	Bupivacaine 2.5mg/ml Solution for Injection
	Bupivacaine 5mg/ml Solution for Injection
Latvia	BUPIVACAINE BAXTER 5 mg/ml šķīdums injekcijām
Lithuania	Bupivacaine Baxter 5mg/ml injekcinis tirpalas
Netherlands	Bupivacaine HCl Baxter 2,5 mg/ml oplossing voor injectie
	Bupivacaine HCl Baxter 5 mg/ml oplossing voor injectie
United Kingdom	Bupivacaine 2.5mg/ml Solution for Injection
	Bupivacaine 5.0mg/ml Solution for Injection

This leaflet was last revised in January 2024.

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

3. Storage information

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

After first opening: to be used immediately.

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.