



MercuryPharma

PATIENT INFORMATION LEAFLET

**Bupivacaine & Adrenaline (Epinephrine) Injection
0.25%w/v, 1 in 200,000**

**Bupivacaine & Adrenaline (Epinephrine) Injection
0.5%w/v, 1 in 200,000**

Anhydrous Bupivacaine Hydrochloride and Adrenaline

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START USING THIS MEDICINE.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The product is known by the above name but will be referred to as Bupivacaine & Adrenaline Injection throughout the rest of this leaflet.

In this leaflet:

1. What Bupivacaine & Adrenaline Injection is and what it is used for
2. Before you are given Bupivacaine & Adrenaline Injection
3. How Bupivacaine & Adrenaline Injection is given to you
4. Possible side effects
5. How to store Bupivacaine & Adrenaline Injection
6. Further information

1. WHAT BUPIVACAINE & ADRENALINE INJECTION IS AND WHAT IT IS USED FOR

Bupivacaine & Adrenaline Injection contains two active ingredients.

- Bupivacaine is a local anaesthetic; it produces loss of feeling or sensation that is confined to one part of the body. Bupivacaine belongs to a group of medicines called amide-type anaesthetics
- Adrenaline narrows the blood vessels at the site of injection which helps to keep the bupivacaine where it is needed for longer.

Bupivacaine & Adrenaline Injection is used in adults and children above 12 years 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
- Relieve pain (0.25% w/v, 1 in 200,000 injection can be used in adults, infants and children above 1 year of age).

It may also be used to give prolonged relief of pain when it is injected around the spinal cord, e.g. as an epidural injection in labour.

2. BEFORE YOU ARE GIVEN BUPIVACAINE & ADRENALINE INJECTION

Do not use

Adrenaline containing Bupivacaine & Adrenaline injection for special techniques (e.g. penile block, Oberst block) to numb parts of the body where areas with end arteries are affected.

You should not be given this medicine if:

- you know you are allergic to bupivacaine or to any other amide-type of local anaesthetic, or to adrenaline, or to any of the other ingredients (see Section 6 of this leaflet)
- you are to be injected in a vein of the hands or legs (Bier's block)
- you suffer from the condition known as thyrotoxicosis (when your body produces too much of the hormone thyroxine)
- you have severe heart disease particularly if it is associated with an increased heart rate.

Because the solution contains adrenaline, which narrows the blood vessels, this injection should not be used in areas such as fingers, toes, ears, nose or penis, as the blood supply to these areas might become inadequate.

You should not be given this injection as an epidural if:

- you have problems with the clotting of your blood or are taking any anticoagulant drugs (e.g. warfarin) that thin the blood
- you have an infection of the skin with pus at or near the site to be injected
- you have inadequate circulation of blood to the heart, sudden loss of blood or weakness of the heart that causes low blood pressure, a weak rapid pulse, sweating and confusion
- you are suffering from any infection, disease or tumour of the brain or spinal cord
- you have bleeding inside the head (intracranial haemorrhage)
- you have increased pressure within the brain.

Speak to your doctor or midwife if one of these applies to you before you are given this medicine.

Take special care and tell your doctor or midwife if:

- you suffer from any liver, severe kidney problems
- you suffer from any heart problem, particularly if it affects the heart rate
- you have breathlessness or restriction to breathing from fluid or a large tumour in the abdomen
- you have high blood pressure or problems with the circulation of blood to the brain
- you have diabetes
- you have a decrease in the amount of fluid circulating in your body causing symptoms such as sweating, mental confusion, dizziness or fainting (for example, due to dehydration or severe bloodloss)
- you suffer from severe shock or low blood pressure
- you have accumulation of fluid around the lungs
- you are elderly (senile)
- you have accumulation of excess fat in your body
- you have excess fluid in the womb during pregnancy (hydraminos)
- you have a tumour of the ovary or the womb
- you suffer from blood poisoning (septicaemia)
- you have an overactive thyroid gland
- you have a tumour of the adrenal glands called a phaeochromocytoma
- you suffer from increased pressure in the eye (glaucoma)
- you have low potassium concentration in the blood
- you have excess calcium in the blood
- you suffer from cancer of the prostate
- you suffer from disorders/damage of the brain.

Taking other medicines:

Tell your doctor or midwife before you are given this medicine if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

A large number of drugs can interact with Bupivacaine & Adrenaline Injection which can significantly alter their effects. These drugs include:

- lidocaine, mexiletine, amiodarone (or any other medicine with local anaesthetic effect) for controlling the heart's rhythm
- medicines to lower your blood pressure including beta-blockers e.g. atenolol, bisoprolol, alpha blockers e.g. phentolamine, adrenergic neurone blockers e.g. guanethidine, potassium depleting diuretics
- medicines which enhance the effects of the sympathetic system such as dopamine
- medicines used to treat allergies such as antihistamines e.g. diphenhydramine
- medicines used to treat heart failure such as cardiac glycosides e.g. digoxin
- medicines used for pain and inflammation such as corticosteroids
- medicines which help you to breathe e.g. aminophylline, theophylline
- medicines used to treat increased blood sugar levels e.g. insulin, oral hypoglycemic agents
- monoamine oxidase inhibitors (MAOI) or tricyclic antidepressants e.g. imipramine both used for depression
- phenothiazines (e.g. chlorpromazine) which are used to treat mental illness
- medicines for Parkinson's disease (such as entacapone)
- doxapram (a medicine which stimulates your breathing)
- oxytocin (a drug which causes the womb to contract and may be used in labour)
- inhaled general anaesthetics, such as halothane
- medicines used to treat thyroid insufficiency such as thyroid hormones. e.g. thyroxine.

If you are already taking one of these medicines, speak to you doctor or midwife before you receive Bupivacaine & Adrenaline Injection.

Space for
Pharmacode

Space for
Pharmacode

continued overleaf

PATIENT INFORMATION LEAFLET

**Bupivacaine & Adrenaline
(Epinephrine) Injection
0.25%w/v, 1 in 200,000**

**Bupivacaine & Adrenaline
(Epinephrine) Injection
0.5%w/v, 1 in 200,000**

Anhydrous Bupivacaine
Hydrochloride and Adrenaline



MercuryPharma

Pregnancy and breast-feeding:

Tell your doctor/midwife before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breast-feeding.

As with all drugs Bupivacaine & Adrenaline Injection should only be given in pregnancy if absolutely necessary. The safety and efficacy of Bupivacaine & Adrenaline injection 0.5%w/v, 1 in 200,000 in children aged < 12 years of age have not been established. Other strengths may be more appropriate.

The safety and efficacy of Bupivacaine & Adrenaline injection 0.25%w/v, 1 in 200,000 in children aged < 1 year of age have not been established.

Driving and using machines:

Certain areas of your body will be numb for about 2-4 hours after having this medicine. If this is likely to affect your ability to drive or use machinery you should wait for the effect to wear off.

In general, it is wise to ask your doctor whether it is safe to drive.

Important information about some of the ingredients of Bupivacaine & Adrenaline Injection:

This medicine contains sodium metabisulphite, a preservative. This may rarely cause severe allergic (hypersensitivity) reactions and wheezing.

This medicinal product contains less than 1mmol sodium (23mg) per dose (essentially 'sodium-free').

3. HOW BUPIVACAINE & ADRENALINE INJECTION IS GIVEN TO YOU

Bupivacaine & Adrenaline Injection should only be administered by a doctor who will, in the case of an epidural injection, have the necessary knowledge and experience in the technique of epidural anaesthesia. Before administering an epidural injection, your doctor may inject a test dose of Bupivacaine & Adrenaline Injection to ensure that the solution is not directed into a blood vessel.

Your doctor will decide on the most suitable dosage for your particular case and may decide to reduce the dose if you are young, or elderly, or in a weak condition.

If you are concerned about how much of this medicine you have received, speak to your doctor immediately.

Use in children and adolescents:

Depending on the type of required analgesia Bupivacaine & Adrenaline injection is injected slowly either into the epidural space (part of the spine) or other parts of the body by an anaesthesiologist experienced in paediatric anaesthetic techniques. Dosage depends on the age and weight of the patient and will be determined by the anaesthesiologist.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bupivacaine & Adrenaline Injection can sometimes cause side-effects, although not everyone gets them.

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Other serious side-effects are also rare, but may occur if too much Bupivacaine & Adrenaline Injection is given or if the drug is unintentionally injected into a blood vessel.

Tell your doctor straight away if you notice any of the following side effects:

Very common - (affects more than 1 in 10 people)

- low blood pressure
- feeling sick (nausea).

Common - (affects less than 1 in 10 people)

- being sick (vomiting)
- dizziness
- pins and needles
- drooping of the upper eyelid, sunk in eye or flushing on the affected side of the face (Horner's syndrome) are most commonly experienced in pregnant women
- slow heart beat
- high blood pressure
- problems passing water.

Uncommon - (affects less than 1 in 100 people)

- fits (convulsions)
- numbness of the tongue
- being sensitive to sound
- loss of consciousness
- light headedness
- difficulty in speaking.
- abnormal sensation of the skin
- ringing in the ears (tinnitus)
- blurred vision (visual disturbances)
- uncontrollable involuntary muscle movement (tremor)
- muscle twitching

Rare - (affects less than 1 in 1,000 people)

- Double vision
- Nerve damage that may cause changes in sensation or muscle weakness. 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 legs
- Spinal cord injury (paraplegia)
- Partial loss of movement (paresis)
- Uneven heart beat or stopped heart beat. This could be life threatening
- Slowed or stopped breathing.

Other possible side effects include:

- problems with your liver enzymes. This may happen if you have long-term treatment with this medicine
- cessation of breathing (apnoea)
- deficiency in the amount of oxygen reaching body tissues (hypoxia)
- more than normal level of carbon dioxide in blood (hypercarbia)
- increased acidity in the blood (acidosis)
- increased potassium levels in the blood (hyperkalemia).

If any of the side effects become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Additional side effects in children and adolescents:

Adverse drug reactions in children are similar to those in adults.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Freephone: 0808 100 3352 (available from 10 a.m. to 2 p.m. Mondays to Fridays)

Website: www.mhra.gov.uk/yellowcard

5. HOW TO STORE BUPIVACAINE & ADRENALINE INJECTION

Keep this medicine out of the sight and reach of children.

The solution should not be used after the expiry date printed on the ampoule and carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Keep the container in the outer carton in order to protect from light.

The solution should not be used if it is discoloured in any way.

This medicine should not be mixed with any other drugs.

The solution must not be stored in contact with metals e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection.

If only part of an ampoule is used, the remaining solution should be discarded.

6. FURTHER INFORMATION

The active substances are bupivacaine hydrochloride and adrenaline.

The other ingredients are sodium metabisulphite (E223), sodium chloride and sodium acetate in water for injections.

What Bupivacaine & Adrenaline Injection looks like and contents of pack

Bupivacaine & Adrenaline Injection is a colourless or almost colourless, aqueous, sterile solution for injection and is available in two strengths:

1. Bupivacaine & Adrenaline Injection 0.25% w/v, 1 in 200,000. Each 10ml of this solution contains 25mg of anhydrous bupivacaine hydrochloride and 50 micrograms of adrenaline.
2. Bupivacaine & Adrenaline Injection 0.5% w/v, 1 in 200,000. Each 10ml of this solution contains 50mg of anhydrous bupivacaine hydrochloride and 50 micrograms of adrenaline.

Both product strengths are available as 10ml glass ampoules in boxes of 10 or individually sterile wrapped in packs of 10.

Marketing authorisation holder

Mercury Pharma International Ltd, 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

This leaflet was last revised in: September 2013.

100417/LF/3-100418/LF/3