Patient leaflet: Information for the patient

Bupivacaine and Adrenaline (Epinephrine) Injection 0.25%w/v, 1 in 200,000
Bupivacaine and Adrenaline (Epinephrine) Injection 0.5%w/v, 1 in 200,000
anhydrous bupivacaine hydrochloride and adrenaline

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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

What is in this leaflet
1. What Bupivacaine & Adrenaline Injection is and what it is used for
2. What you need to know 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. Contents of the pack and other 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. What you need to know before you are given Bupivacaine & Adrenaline Injection
Bupivacaine & Adrenaline Injection should not be given to you
- if you are allergic to bupivacaine & adrenaline, or to any other amide-type of local anaesthetic or any of the other ingredients of this medicine (listed in section 6).
- for special techniques (e.g. penile block, Oberst block) to numb parts of the body where areas with end arteries are affected.
- if you are to be injected in a vein of the hands or legs (Bier's block)
- if you suffer from the condition known as thyrotoxicosis (when your body produces too much of the hormone thyroxine)
- if 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 Bupivacaine & Adrenaline 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
• if you have an infection of the skin with pus at or near the site to be injected
• if 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
• if you are suffering from any infection, disease or tumour of the brain or spinal cord
• if you have bleeding inside the head (intracranial haemorrhage)
• if 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.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Bupivacaine & Adrenaline Injection
• if you suffer from any liver, severe kidney problems
• if you suffer from any heart problem, particularly if it affects the heart rate
• if you have a condition called congenital long QT syndrome or problems with heart rhythm
• if you have breathlessness or restriction to breathing from fluid or a large tumour in the abdomen
• if you have high blood pressure or problems with the circulation of blood to the brain
• if you have diabetes
• if 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 blood loss)
• if you suffer from severe shock or low blood pressure
• if you have accumulation of fluid around the lungs
• if you are elderly (senile)
• if you have accumulation of excess fat in your body
• if you have excess fluid in the womb during pregnancy (hydraminos)
• if you have a tumour of the ovary or the womb
• if you suffer from blood poisoning (septicaemia)
• if you have an overactive thyroid gland
• if you have a tumour of the adrenal glands called a phaeochromocytoma
• if you suffer from increased pressure in the eye (glaucoma)
• if you have low potassium concentration in the blood
• if you have excess calcium in the blood
• if you suffer from cancer of the prostate
• if you suffer from disorders/damage of the brain.

Other medicines and Bupivacaine & Adrenaline Injection:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

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.

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.

Bupivacaine & Adrenaline Injection contains
Sodium metabisulphite
This medicine contains sodium metabisulphite, which may rarely cause severe hypersensitivity reactions and bronchospasm.

Sodium
Bupivacaine & Adrenaline (Epinephrine) Injection 0.25%w/v, 1 in 200,000 contains 200.88 mg sodium (main component of cooking/table salt) in each 150 mg of dose. This is equivalent to 0.05% of the recommended maximum daily dietary intake of sodium for an adult.

Bupivacaine & Adrenaline (Epinephrine) Injection 0.5%w/v, 1 in 200,000 contains 98.34 mg sodium (main component of cooking/table salt) in each 150 mg of dose. This is equivalent to 4.92% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Bupivacaine and 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 administrating 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 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.

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 or pharmacist immediately if you experience any of the following serious side effects:
• loss of consciousness
• uneven heart beat or stopped heart beat. This could be life threatening

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

Very common: may affect more than 1 in 10 people
• low blood pressure
• feeling sick (nausea).

Common: may affect up to 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: may affect up to 1 in 100 people
• fits (convulsions)
• abnormal sensation of the skin
• numbness of the tongue
• ringing in the ears (tinnitus)
• being sensitive to sound
• blurred vision (visual disturbances)
• uncontrollable involuntary muscle movement (tremor)
• light headedness
• muscle twitching

• difficulty in speaking.

Rare: may affect up to 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)
• 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).

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bupivacaine and Adrenaline Injection

Keep this medicine out of the sight and reach of children.
This medicine 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. Contents of the pack and other information

What Bupivacaine & Adrenaline Injection contains

- 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 the pack

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

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