Bupivacaine Hydrochloride Injection 0.25%w/v. Each 1ml contains 2.5mg of anhydrous bupivacaine hydrochloride. Bupivacaine Hydrochloride Injection is a colourless or almost colourless, aqueous, sterile solution for injection. The other ingredients are sodium chloride and sodium hydroxide and water for injection.

The active substance is bupivacaine hydrochloride.

Bupivacaine Hydrochloride Injection may be used as follows:
- relieve pain in adults, infants and children above 1 year of age.
- numb parts of the body during surgery in adults and children above 12 years
- 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.
Bupivacaine Hydrochloride Injection may be used as follows:
- as a local injection to produce numbness at the site of injection
- injected around a nerve to block the nerve and relieve pain
- injected around the spinal cord as an epidural to prevent or relieve pain, e.g. in labour, surgical operations including Caesarean section, and for post-operative pain.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet, please tell your doctor or midwife.

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.

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 you have any further questions, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

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

KEEP THIS LEAFLET.

This product will be referred to as Bupivacaine Hydrochloride Injection from here on.

In this leaflet:
1. WHAT BUPIVACAINE HYDROCHLORIDE INJECTION IS AND WHAT IT IS USED FOR
2. BEFORE YOU ARE GIVEN BUPIVACAINE HYDROCHLORIDE INJECTION
3. HOW BUPIVACAINE HYDROCHLORIDE INJECTION IS GIVEN TO YOU
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE BUPIVACAINE HYDROCHLORIDE INJECTION
6. FURTHER INFORMATION
7. PATIENT INFORMATION LEAFLET

Bupivacaine belongs to a group of medicines called amide-type anaesthetics. Bupivacaine Hydrochloride injection 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.
Bupivacaine Hydrochloride Injection may be used as follows:
- as a local injection to produce numbness at the site of injection
- injected around a nerve to block the nerve and relieve pain
- injected around the spinal cord as an epidural to prevent or relieve pain, e.g. in labour, surgical operations including Caesarean section, and for post-operative pain.

Bupivacaine Hydrochloride Injection and 0.5%w/v solution for Injection and 0.25% w/v solution for Injection

Bupivacaine Hydrochloride Injection 0.5%w/v. Each 1ml contains 5mg of anhydrous bupivacaine hydrochloride.

The active substance is bupivacaine hydrochloride. The other ingredients are sodium chloride and sodium hydroxide and water for injection.

Bupivacaine Hydrochloride Injection 0.25%w/v solution for Injection and 0.5% w/v solution for Injection

Bupivacaine Hydrochloride Injection 0.25%w/v. Each 1ml contains 2.5mg of anhydrous bupivacaine hydrochloride.

The active substance is bupivacaine hydrochloride. The other ingredients are sodium chloride and sodium hydroxide and water for injection.

Bupivacaine Hydrochloride Injection 0.5%w/v. Each 1ml contains 5mg of anhydrous bupivacaine hydrochloride.

Both product strengths are available as either:
- 10ml and 20ml clear plastic (polypropylene) ampoules in packs of 10, 20, 50 or 100, or
- 10 and 20 individual sterile wrapped clear plastic (polypropylene) ampoules in packs of 10, 20, 50 or 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mercury Pharmaceuticals Ltd,
Capital House, 85 King William Street, London EC4N 7BL, UK

Manufacturer
Curida AS, Solbaervegen 5, NO-2409, Elverum, Norway.

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PATIENT INFORMATION LEAFLET
Bupivacaine Hydrochloride 0.25%w/v solution for Injection and 0.5% w/v solution for Injection

This leaflet was last revised in:

December 2018.
Tell your doctor or midwife before you are given this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or are breastfeeding. There is no evidence of harmful effects in pregnancy or breastfeeding. However, as with all drugs Bupivacaine Hydrochloride Injection should only be given in early pregnancy if absolutely necessary.

Use in children and adolescents

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bupivacaine Hydrochloride 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 Hydrochloride Injection is given or if the drug is unintentionally injected into a blood vessel. If you notice any of the following effects inform your doctor immediately.

Other possible side effects

Very common (affects more than 1 in 10 people):
• Low blood pressure. This might make you feel dizzy or light-headed
• Feeling sick (Nausea)

Common (affects 1 to 10 people in 100)
• Being sick (Vomiting)
• Feeling dizzy
• Pins and needles
• High blood pressure
• Slow heartbeat
• Problems in passing water
• Drooping of the upper eyelid, sunken in eye, flushing of the face (Horner’s syndrome) are more commonly experienced in pregnant women.

Uncommon (affects 1 to 10 people in 1000)
• Feeling light-headed
• Fills
• Ringing in the ears or being sensitive to sound
• Difficulty in speaking
• Numbness of the tongue
• Blurred sight
• Loss of consciousness
• Shaking
• Twitching of your muscles.

Rare (affects 1 to 10 people in 10,000)
• 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 (paralysis)