

Package leaflet: Information for the user

Bupivacaine Hydrochloride 1 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion Bupivacaine Hydrochloride 1.25 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion

bupivacaine hydrochloride/fentanyl citrate

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.

The name of your medicine is Bupivacaine Hydrochloride 1 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion and Bupivacaine Hydrochloride 1.25 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion. It will be referred to as Bupivacaine and Fentanyl infusion for ease hereafter.

What is in this leaflet

1. What Bupivacaine and Fentanyl infusion is and what it is used for
2. What you need to know before you are given Bupivacaine and Fentanyl infusion
3. How Bupivacaine and Fentanyl infusion will be given to you
4. Possible side effects
5. How to store Bupivacaine and Fentanyl infusion
6. Contents of the pack and other information

This medicine contains fentanyl which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Bupivacaine and Fentanyl infusion is and what it is used for

This medicine is a mixture of two active ingredients: Bupivacaine, which is a local anaesthetic, a medicine used to numb areas of your body in order to relieve pain and Fentanyl (as citrate), which is used to treat pain.

This medicine has been prescribed for you for the treatment of pain during labour and after operations. It contains fentanyl which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been provided to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely. It will be given to you in hospital under the supervision of an anaesthetist, in an epidural (injection into the lower back).

2. What you need to know before you are given Bupivacaine and Fentanyl infusion

You should not be given Bupivacaine and Fentanyl infusion by an epidural if you:

- are allergic to bupivacaine, fentanyl or any of the other ingredients of this medicine (listed in section 6)
- have been given a type of local anaesthesia known as a Bier's block
- have been given a type of local anaesthesia that numbs the cervix during childbirth
- are suffering from inflammation or skin infection at the site of the proposed injection

- have problems with blood clotting or you are taking medicines to stop your blood clotting
- have a heart problem known as complete heart block
- are currently having difficulty breathing or you suffer from asthma
- have suffered a head injury or are suffering from a disease that affects the brain or the nerves in your spine such as meningitis, poliomyelitis, brain or spinal tumours, developmental spinal problems such as spina bifida, tuberculosis of the spine, blood vessel malformations or bleeding in the brain
- are suffering from shock caused by a lack of blood or problems with your blood circulation (symptoms of this include feeling weak, cold or pale skin, breathing quickly and anxiety)
- are currently taking drugs used to treat depression known as monoamine oxidase inhibitors (MAOIs) or have taken them in the last 2 weeks
- have consumed excessive amounts of alcohol
- are suffering from a blood disorder known as pernicious anaemia.

Warnings and precautions

Talk to your doctor or nurse before you are given Bupivacaine and Fentanyl infusion if you have:

- a disorder that causes fits such as epilepsy
- any heart problems including, low or high blood pressure, fast or slow heartbeats
- liver or kidney problems
- problems with your adrenal glands
- problems with your thyroid
- prostate enlargement in men
- disease of the nervous system, such as Myasthenia gravis (a disorder with weak muscles)
- breathing problems
- you are taking any medicine from the group of medicines known as benzodiazepines. Taking these medicines with Bupivacaine and Fentanyl infusion may result in sedation, difficulties in breathing (respiratory depression), coma and may be fatal. Even if benzodiazepines are prescribed, your doctor may need to change the dose, the duration of treatment or monitor you regularly.

Talk to your prescriber before taking this medicine if you:

- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”)
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs
- feel you need to take more of Bupivacaine and Fentanyl infusion to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

If your treatment is stopped withdrawal symptoms may occur. Please tell your doctor or nurse if you think this is happening to you (see also section 4. Possible side effects).

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking,

shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Bupivacaine and Fentanyl infusion, it is important that you consult your doctor.

In particular, tell your doctor or pharmacist if you are taking:

- some painkillers for nerve pain (gabapentin and pregabalin).

Special care will be taken when this medicine is being given to the elderly and ill. If any of the above apply to you, please consult your doctor.

Other medicines and Bupivacaine and Fentanyl infusion

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including those obtained without prescription.

You **must not** be given Bupivacaine and Fentanyl infusion if you are taking:

- drugs used to treat severe depression, such as phenelzine or moclobemide or if you have stopped taking them within the last 2 weeks. These drugs are known as Monoamine Oxidase Inhibitors (MAOIs)
- medicines used to stop your blood clotting (anticoagulants).

Tell your doctor if you are taking any of the following medicines which may interact with Bupivacaine and Fentanyl infusion:

- medicines used to treat irregular heartbeats such as amiodarone
- medicines that depress the nervous system such as sleeping pills or those that may cause drowsiness or are used to help you to relax (anxiolytics) such as barbiturates
- medicines used to treat mental disorders (antipsychotics) such as chlorpromazine and droperidol
- medicines used to treat high blood pressure such as propranolol
- general anaesthetics such as propofol and nitrous oxide
- strong painkillers such as morphine and codeine
- cimetidine which is used to treat stomach ulcers
- the antiviral drug ritonavir
- concomitant use of Bupivacaine and Fentanyl infusion and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Bupivacaine and Fentanyl infusion together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you have any doubts about whether this medicine should be given to you, consult your doctor, nurse or pharmacist.

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 for advice before being given this medicine.

Pregnancy

Do not take Bupivacaine and Fentanyl infusion if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Bupivacaine and Fentanyl infusion during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breastfeeding

Do not take Bupivacaine and Fentanyl infusion while you are breastfeeding as fentanyl passes into breast milk and will affect your baby.

Driving and using machines

Bupivacaine and Fentanyl infusion may affect your ability to drive or operate machinery. If you are discharged from hospital soon after receiving this medicine and plan to resume these activities, ask your doctor when it will be safe to do so.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- do not drive while using this medicine until you know how it affects you
- it is an offence to drive if this medicine affects your ability to drive
- however, you would not be committing an offence if:
 - the medicine has been prescribed to treat a medical or dental problem and
 - you have received it according to the instructions given by the prescriber or in the information provided with the medicine and
 - it was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while you are given this medicine.

Bupivacaine and Fentanyl infusion contains sodium

- Bupivacaine Hydrochloride 1 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion contains 867 mg sodium (main component of cooking/table salt) in each 250 ml of solution.
- Bupivacaine Hydrochloride 1.25 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion contains 862 mg sodium (main component of cooking/table salt) in each 250 ml of solution.

This is equivalent to about 43% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Bupivacaine and Fentanyl infusion will be given to you

Your prescriber should have discussed with you, how long the course will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Bupivacaine and Fentanyl infusion should only be administered by a doctor who will, in the case of an epidural infusion, have the necessary knowledge and experience in the technique of epidural anaesthesia.

Before administering an epidural infusion solution, your doctor may inject a test dose of Bupivacaine and Fentanyl infusion 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 elderly or in a weak condition or if you have liver or kidney problems. If you are

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

Use in children:

Bupivacaine and Fentanyl infusion is not recommended for use in children.

If you stop taking Bupivacaine and Fentanyl infusion

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you are given more Bupivacaine and Fentanyl than you should be

An overdose may result in a brain disorder known as toxic leukoencephalopathy.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause severe potentially life-threatening 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), shock should be reported to a doctor immediately.

If you notice any of the following side effects speak to your doctor, pharmacist or nurse **as soon as possible:**

- signs and symptoms of nervous system toxicity such as sense of intense excitement and happiness (euphoria), disorientation, numbness of the tongue, increased sensitivity to sounds (hyperacusis), visual disturbances, loss of consciousness, shakiness/tremor, light headedness, ringing or buzzing in the ears (tinnitus), severe itching of the skin (pruritus), excessive perspiration (diaphoresis), speech disorder (dysarthria), muscle twitching
- heart attack (cardiac arrest), irregular heartbeat (cardiac arrhythmia)
- changes in mood
- seeing or hearing things (hallucinations)
- uncontrolled spasm of your vocal chords (laryngospasm)
- hypoventilation/slowed breathing (respiratory depression)
- convulsions.

Other possible side effects include:

Very common (may affect more than 1 in 10 people):

- low blood pressure (hypotension)
- muscle rigidity (which may involve chest muscle)
- feeling sick (nausea)
- being sick (vomiting).

Common (may affect up to 1 in 10 people):

- nervousness
- abnormal sensation in peripheral nerves (paraesthesia)
- dizziness
- decreased heart rate (bradycardia)

- hypertension
- difficulty in urination (urinary retention)
- anxiety (agitation)
- impairment of voluntary movement (dyskinesia), sedation, dizziness, drowsiness, confusion
- visual disturbances
- rapid heart rate (tachycardia)
- venous pain
- spasm of bronchial smooth muscle (bronchospasm)
- difficulty in breathing (apnoea)
- allergic skin condition caused by inflammation of skin (allergic dermatitis)
- postoperative confusion.

Uncommon (may affect up to 1 in 100 people):

- headache, facial flushing, sensation of loss of balance (vertigo), restlessness
- excessive constriction of pupil of eye (miosis)
- rapid, strong or irregular heartbeat (palpitations)
- inflammation of the walls of a vein (phlebitis)
- blood pressure fluctuation
- fall in blood pressure after suddenly standing up from a lying or sitting position (orthostatic hypotension)
- rapid breathing (hyperventilation)
- hiccups
- dry mouth
- difficulty in swallowing
- constipation
- chills, cold (hypothermia), sweating, micturition difficulties
- airway complication of anaesthesia.

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

- weakness, loss of sensation (persistent anaesthesia), bowel incontinence (loss of sphincter control), weakness or numbness in peripheral nerves (neuropathy), peripheral nerve injury, a pain disorder caused by inflammation of one of the membranes that surrounds and protects the nerves of the spinal cord. It is characterized by severe stinging, burning pain, and neurological problems (arachnoiditis), muscular weakness caused by nerve damage (paresis), paralysis of legs and lower body (paraplegia)
- double vision (diplopia).

Not known (frequency cannot be estimated from the available data):

- loss of consciousness, involuntary twitching of a muscle (myoclonus), impairment of voluntary movement (Dyskinesia), rise in the pressure inside the skull that can result from or cause brain injury (raised intracranial pressure)
- cough
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- dependence and addiction (see section “How do I know if I am addicted?”).
- drug withdrawal - symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: restlessness, difficulty sleeping, irritability, agitation, nausea, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, vomiting, diarrhoea, anxiety, chills, tremor, shaking shivering or sweating)

How do I know if I am addicted?

If you notice any of the following signs whilst taking Bupivacaine and Fentanyl infusion, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber.
- You feel you need to use more than the recommended dose.
- You are using the medicine for reasons other than prescribed.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber

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: <https://yellowcard.mhra.gov.uk/> 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 Fentanyl infusion

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

You should not be given Bupivacaine and Fentanyl infusion after the expiry date which is stated on the container label after EXP.

The doctor or nurse will check that the expiry date on the label has not been passed before administering the infusion to you. The expiry date refers to the last day of that month.

Your doctor or the hospital will store this medicine and are responsible for the quality of the product when it is opened if not used immediately. They are also responsible for correctly disposing of any unused solution. 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 protect the environment.

6. Contents of the pack and other information

What Bupivacaine and Fentanyl infusion contains

The active substances are bupivacaine hydrochloride and fentanyl (as citrate).

- **Bupivacaine Hydrochloride 1 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion:** Each 1 ml contains 1 mg of bupivacaine hydrochloride and 2 micrograms of fentanyl.
- **Bupivacaine Hydrochloride 1.25 mg/ml and Fentanyl Citrate 2 micrograms/ml Solution for infusion:** Each 1 ml contains 1.25 mg of bupivacaine hydrochloride and 2 micrograms of fentanyl.

The other ingredients are sodium chloride, sodium hydroxide and water for injections.

What Bupivacaine and Fentanyl infusion looks like and contents of the pack:

Bupivacaine and Fentanyl infusion is a clear, colourless aqueous sterile solution for infusion and is available in two strengths: Both product strengths are available as 250 ml or 500 ml plastic (polypropylene) bags for infusion in packs of 5.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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