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MercuryPharma

Package leaflet: Information for the user

BUFYL® 1mg/ml and 2 microgram/ml Solution for infusion
BUFYL® 1.25mg/ml and 2 microgram/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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is BUFYL® 1mg/ml and 2 microgram/ml Solution for infusion and BUFYL® 1.25mg/ml and 2 microgram/ml Solution for infusion. It will be referred to as Bufyl for ease hereafter.

What is in this leaflet

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

1. WHAT BUFYL 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. Bufyl is a medicine that is used to treat pain during labour and after operations. 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 BUFYL

You should not be given Bufyl by an epidural
- if you are allergic to bupivacaine, fentanyl or any of the other ingredients of this medicine (listed in section 6)
- if you have been given a type of local anaesthesia known as a Biers block
- if you have been given a type of local anaesthesia that numbs the cervix during childbirth
- if you are suffering from inflammation or skin infection at the site of the proposed injection
- if you have problems with blood clotting or you are taking medicines to stop your blood clotting
- if you have a heart problem known as complete heart block
- if you are currently having difficulty breathing or you suffer from asthma
- if you 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
- if you 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)
- if you are currently taking drugs used to treat depression known as monoamine oxidase inhibitors (MAOIs) or have taken them in the last 2 weeks
- if you have consumed excessive amounts of alcohol
- if you are suffering from a blood disorder known as pernicious anaemia.

Warnings and precautions
Talk to your doctor or nurse before you are given Bufyl 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 Bufyl 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.

Tell your doctor if you have ever abused or been dependent on opioids, alcohol, prescription medicines, or illegal drugs.

Repeated use of the product may result in the drug being less effective (you become accustomed to it) or becoming dependent on it.

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).

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 Bufyl
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 Bufyl 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 that may interact with Bufyl:
- 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 Bufyl 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 Bufyl 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.

Driving and using machines
Bufyl 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.

3. HOW BUFYL WILL BE GIVEN TO YOU

Bufyl 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 administrating an epidural infusion solution, your doctor may inject a test dose of Bufyl 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:
Bufyl is not recommended for use in children.

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, nurse or pharmacist **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
- 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 anasthesia), 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)
- symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating).

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

Reporting of side effects
If you get any side effects, talk to your doctor 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 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 BUFYL

Keep this medicine out of the sight and reach of children.
You should not be given Bufyl 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.
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 Bufyl contains
- The active substances are bupivacaine hydrochloride and fentanyl (as citrate).
  Bufyl 1mg/ml and 2microgram/ml Solution for Infusion: Each 1ml contains 1mg of bupivacaine hydrochloride and 2 micrograms of fentanyl.
  Bufyl 1.25mg/ml and 2microgram/ml Solution for Infusion: Each 1ml contains 1.25mg of bupivacaine hydrochloride and 2 micrograms of fentanyl.
- The other ingredients are:
  - Sodium chloride and sodium hydroxide contains less than 1mmol sodium (23mg) per ml, i.e. it is essentially 'sodium-free'.
  - Water for injections.

What Bufyl looks like and contents of the pack:
Bufyl is a clear, colourless aqueous sterile solution for infusion and is available in two strengths:
Both product strengths are available as 250ml or 500ml plastic (polypropylene) bags for infusion in packs of 5, not all pack sizes may be marketed.

Marketing Authorisation Holder
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