• blood pressure fluctuation
• fall in blood pressure after suddenly standing up from a lying or sitting position (orthostatic hypotension)
• rapid breathing (hyperventilation)
• tics
• dry mouth
• constipation
• chills, cold (hypothermia), sweating, micturition difficulties
• anxious compulsion 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 stringing, burning pain and neurological problems (arachnoiditis), muscular weakness caused by nerve damage (paralysis), 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.

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.
• 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.
• 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.

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.

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.

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 administering 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)
• uncontrollable 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 (dyskinesias), 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)