PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION

Bupivacaine Hydrochloride 5mg/ml + Dextrose Monohydrate 80mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. WHAT BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION IS AND WHAT IT IS USED FOR

Bupivacaine Hydrochloride + Dextrose Monohydrate Injection (Bupivacaine Heavy) is indicated in adults and children of all ages for intrathecal (subarachnoid) spinal anaesthesia for surgery (urological and lower limb surgery lasting 2 - 3 hours, abdominal surgery lasting 45 - 60 minutes).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION

Contraindication:

The Product is contraindicated in the following situations:

- Hypersensitivity to local anaesthetics of the amide type or to any of the excipients.
- Active diseases of the central nervous system such as meningitis, poliomyelitis, intracranial haemorrhage, sub - acute combined degeneration of the cord due to pernicious anaemia and cerebral and spinal tumours.
- Spinal stenosis and active disease (e.g. spondylitis, tuberculosis, tumour) or recent trauma (e.g. fracture) in the vertebral column.
- Septicaemia.
- Pyogenic infection of the skin at or adjacent to the site of lumbar puncture.
- Cardiogenic or hypovolaemic shock.
- Coagulation disorders or ongoing anticoagulation treatment.

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Warnings and precautions

- Intrathecal anaesthesia should only be undertaken by clinicians with the necessary knowledge and experience.
- Regional anaesthetic procedures should always be performed in a properly equipped and staffed area. Resuscitative equipment and drugs should be immediately available and the anaesthetist should remain in constant attendance.
- Intravenous access, e.g. an I.V infusion, should be in place before starting the intrathecal anaesthesia. The clinician responsible should take the necessary precautions to avoid intravascular injection and be appropriately trained and familiar with the diagnosis and treatment of side effects, systemic toxicity and other complications. If signs of acute systemic toxicity or total spinal block appear, injection of the local anaesthetic should be stopped immediately.
- Like all local anaesthetic drugs, Bupivacaine hydrochloride may cause acute toxicity effects on the central nervous and cardiovascular systems, if utilised for local anaesthetic procedures resulting in high blood concentrations of the drug. This is especially the case after unintentional intravascular administration or injection into highly vascular areas.
- Ventricular arrhythmia, ventricular fibrillation, sudden cardiovascular collapse and death have been reported in connection with high systemic concentrations of Bupivacaine. Should cardiac arrest occur, a successful outcome may require prolonged resuscitative efforts. High systemic concentrations are not expected with doses normally used for intrathecal anaesthesia.
- There is an increased risk of high or total spinal blockade, resulting in cardiovascular and respiratory depression, in the elderly and in patients in the late stages of pregnancy. The dose should therefore be reduced in these patients. Intrathecal anaesthesia with any local anaesthetic can cause hypotension and bradycardia which should be anticipated and appropriate precautions taken. These may include preloading the circulation with crystalloid or colloid solution. If hypotension develops it should be treated with a vasopressor such as ephedrine 10-15 mg intravenously. Severe hypotension may result from hypovolaemia due to haemorrhage or dehydration, or aortocaval occlusion in patients with massive ascites, large abdominal tumours or late pregnancy. Marked hypotension should be avoided in patients with cardiac decompensation.
- Patients with hypovolaemia due to any cause can develop sudden and severe hypotension during intrathecal anaesthesia. Intrathecal anaesthesia can cause intercostal paralysis and patients with pleural effusions may suffer respiratory embarrassment. Septicaemia can increase the risk of intraspinal abscess formation in the postoperative period.
- Neurological injury is a rare consequence of intrathecal anaesthesia and may result in paraesthesia, anaesthesia, motor weakness and paralysis. Occasionally these are permanent.
- Before treatment is instituted, consideration should be taken if the benefits outweigh the possible risks for the patient.
- Patients in poor general condition due to ageing or other compromising factors such as

partial or complete heart conduction block, advanced liver or renal dysfunction require special attention, although regional anaesthesia may be the optimal choice for surgery in these patients.

- Patients treated with anti-arrhythmic drugs class III (e.g. amiodarone) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

Other medicines and Bupivacaine Hydrochloride + Dextrose Monohydrate
Bupivacaine hydrochloride should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. certain antiarrhythmics, such as lidocaine and mexiletine, since the systemic toxic effects are additive. Specific interaction studies with Bupivacaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised.

Pregnancy, breast-feeding and fertility.
Pregnancy:
There is no evidence of untoward effects in human pregnancy. In large doses, there is evidence of decreased pup survival in rats and an embryological effect in rabbits if Bupivacaine hydrochloride is administered in pregnancy. Bupivacaine Hydrochloride + Dextrose Monohydrate Injection should not therefore be given in early pregnancy unless the benefits are considered to outweigh the risks. It should be noted that the dose should be reduced in patients in the late stages of pregnancy.

Lactation:
Bupivacaine hydrochloride passes into breast milk, but the risk of this affecting the child appears unlikely with therapeutic doses.

Driving and using machines
Bupivacaine hydrochloride has a transient effect on movement and coordination.

3. HOW TO USE BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION

Bupivacaine Hydrochloride + Dextrose Monohydrate Injection (Bupivacaine Heavy) should only be used by clinicians with experience of regional anaesthesia or under their supervision. The lowest possible dose for adequate anaesthesia should be used. The doses given below are guides for adults and the dosage should be adjusted to the individual patients.

Adults and children above 12 years of age
The doses recommended below should be regarded as a guide for use in the average adult. The figures reflect the expected average dose range needed. Standard reference books should be consulted for factors affecting specific block techniques and for individual patient requirements.

Dosage recommendations
Intrathecal anaesthesia for surgery:
2 - 4 ml (10 - 20 mg Bupivacaine Hydrochloride).
The dose should be reduced in elderly patients and patients in the late stages of pregnancy.

Neonates, infants and children up to 40 kg
Bupivacaine Hydrochloride + Dextrose Monohydrate Injection (Bupivacaine Heavy) may be used in children. One of the differences between small children and adults is a relatively high CSF volume in infants and neonates, requiring a relatively larger dose/kg to produce the same level of blocks as compared to adults.

Paediatric regional anaesthesia procedures should be performed by qualified clinicians who are familiar with this population and the techniques. The doses in the table below should be regarded as guidelines for use in paediatric patients. Individual variations occur. The lowest dose required for adequate should be used.

Dosage recommendations in neonates, infants and children

Body weight (kg)	**Dose (mg/kg)**
<5	0.40 - 0.50 mg/kg
5 to 15	0.30 - 0.40 mg/kg
16 to 40	0.25 - 0.30 mg /kg

The spread of anaesthesia obtained with Bupivacaine Hydrochloride + Dextrose Monohydrate Injection depends on several factors including the volume of solution and the position of the patient during and following the injection.

When injected at the L3 – L4 intevertebral space, with the patients in the sitting position, 3 ml of Bupivacaine Hydrochloride + Dextrose Monohydrate Injection to the T7 – T10 spinal segments. With the patient receiving the injection in the horizontal position and then turned supine, the blockade spreads to T4 – T7 spinal segments. It should be understood that the level of spinal anaesthesia archived with any local anaesthetic can be unpredictable in a given patient.

The recommended site of injection is below L3. The effects of injections of Bupivacaine Hydrochloride + Dextrose Monohydrate Injection exceeding 4 ml have not yet been studied and such volumes can therefore not be recommended.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

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 less than 1 in 10 people)
- Feeling dizzy
- Vomiting
- High blood pressure (hypertension)
- Slow heart beat
- Problems passing Urine.

Uncommon (affects less than 1 in 100 people)
- Feeling light-headed
- Fits (seizures)
- Numbness of the tongue or around the mouth
- Abnormal sensation of the skin around the mouth
- Ringing in the ears or being sensitive to sound
- Difficulty in speaking
- Blurred sight or double vision
- Loss of consciousness
- Shaking (tremors).
- Twitching of your muscles

Rare (affects less than 1 in 1,000 people)
- Nerve damage that may cause changes in sensation or muscles weakness (neuropathy). 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 the legs
- Spinal cord injury (paraplegia)
- Weak or paralysed legs
- Double vision
- Uneven heartbeat (arrhythmias). This could be life-threatening.
- Slowed or stopped breathing or stopped heartbeat. This could be life-threatening**.**

Possible side effects seen with other local anaesthetics which may also be caused by Bupivacaine Hydrochloride + Dextrose Monohydrate Injection may include:
- Problems with your liver enzymes. This may happen if you have long-term treatment with this medicine
- Collection of pus in the spinal cord
- Loss of sensation

- 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)
- Low levels of calcium in the blood (hypocalcaemia)
- Damaged nerves. Rarely this may cause permanent problems.
- Blindness which is not permanent or problems with the muscles of the eyes that are long-lasting. This may happen with some injections given around the eyes.
- Drooping of the upper eyelid, sunk in eye or flushing on the affected side of the face (Horner' syndrome) are most commonly experienced in pregnant women.

Additional side effects in children and adolescents
Adverse drug reactions in children are like those in adults.

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.

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.

5. HOW TO STORE BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not use Bupivacaine Hydrochloride + Dextrose Monohydrate Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION contains
Each ml of Bupivacaine Hydrochloride + Dextrose Monohydrate Injection contains 5mg of Bupivacaine Hydrochloride

What BUPIVACAINE HYDROCHLORIDE + DEXTROSE MONOHYDRATE INJECTION looks like and contents of the pack
Clear transparent liquid in 10x4ml Ampoules packed in an inner carton

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SUPPLIER AND MANUFACTURER
Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.
234-(0)8077008888
Customercare@fidson.com

	Prepared by	Approved by	
Signature			
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