Description: Nerkein® injectioin is a preparation of bupivacaine, a long acting local anaesthetic agent that belongs to amide group. It blocks the generation and the conduction of nerve impulses, by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.

Indication: Nerkein® injectioin is used for pain management in the postoperative setting and other situations where therapeutic pain blockade is required. It is used for a number of different types of anaesthesia including: infiltration anaesthesia (where it can be injected directly into the site where the procedure will occur), peripheral sympathetic nerve anaesthesia, epidural anaesthesia, surgical anaesthesia, obstetric anaesthesia. Due to its long duration of action, Bupivacaine is especially useful in situations where long acting anaesthesia is needed.

Dosage and Administration: The dosage varies and depends upon the area to be anaesthetised, vascularity of the tissues, number of neuronal segments to be blocked, individual tolerance and the technique used. The lowest dose required to provide effective anaesthesia should be administered. For specific techniques and procedures, refer to standard textbooks.

The dose of bupivacaine at any time should not exceed 2 mg/kg bodyweight. The normal recommended dose of plain bupivacaine injections for various anaesthetic procedures in the average, healthy 70 kg adult patient are as follows:

Procedure	**Dose Range**	**Concentration used (%)**	**Volume (mL) Required**
Infiltration	12.5-150 mg	0.25	5-60 ml
		0.5	5-30 ml
Minor peripheral nerve blocks	12.5-100 mg	0.25	5-30 ml
		0.5	5-20 ml
Major peripheral nerve blocks	50-150 mg	0.25	20-40 ml
		0.5	20-30 ml
Coeliac Block	100-125 mg	0.25	40-50 ml
Epidural block			
Lumbar	75-100 mg	0.5	15-20 ml
Caudal	75-125 mg	0.25	15-40 ml
		0.5	15-25 ml
Intercostal Block (per segment)	10-25 mg	0.25	4-8 mL/seg
		0.5	3-5 mL/seg
Hip Joint Block		0.5	3-5 mL/seg
Sciatic	100-150 mg	0.5	20-30 ml
Femoral	50-100 mg	0.5	10-20 ml
Obturator	50-100 mg	0.5	10-20 ml
Lateral Cutaneous	12.5-25 mg	0.25	5-10 ml
Obstetrics/Gynaecology			

Epidural/caudal (vaginal delivery etc.)	15-60 mg	0.25-0.5	6-12 ml
Epidural (caesarean section/hysterectomy)	5-150 mg	15-30	
Pudendal	12.5-50 mg	0.25-0.5	5-10 each side
Postoperative Analgesia			
Intermittent epidural	20-40 mg (1-2/hr)	0.5	4-8 (1-2/hr)
Continuous epidural	18.75 mg/hr	0.125	15/hr

* given either as a single or incremental dose

Side Effects: Serious side effects are rare. The common side effects are nausea,vomiting, tinnitus, numbness, nervousness, blurred vision, tremor, dizziness and disorientation.

Contraindications: Bupivacaine is contraindicated in patients with a known hypersensitivity to it or to any local anaesthetic agents of the amide type. It is contraindicated in intra-venous regional anaesthesia (Bier block), in obstetrical paracervical block anaesthesia and in all intravenous infusions. It is also contraindicated In the presence of inflammation and/or other infection at the proposed injection site, and in the presence of septicemia

Precaution: Readiness for emergencies.The lowest dosage that gives effective anaesthesia should be used in order to avoid high plasma levels and serious systemic side effects. Injection of repeated doses of Bupivacaine Hydrocholoride may cause significant increase in blood levels with each additional dose, due to accumulation of the drug or its metabolites or due to slow metabolic degradation. Tolerance varies with the status of the patient. Debilitated, elderly patients and acutely ill patients should be given reduced doses commensurate with age and physical condition. Caution is advised in administration of repeat doses of Bupivacaine Hydrocholoride to patients with severe liver disease.Local anaesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.

Pregnancy and Lactation: There are no adequate and well-controlled studies in pregnant women of the effect of bupivacaine hydrochloride on the developing fetus. Bupivacaine should not therefore be given in early pregnancy only if the potential benefit justifies the potential risk to the fetus. Bupivacaine enters the mother's milk, but in such small quantities that there is no risk of affecting the child at therapeutic dose levels.

Labor and Delivery: Bupivacaine hydrochloride is contraindicated for obstetrical paracervical block anesthesia. Local anaesthetics rapidly cross the placenta, and when used for epidural, caudal, or pudendal block anaesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity. The incidence and degree of toxicity depend upon the procedure performed, the type, and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus, and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.

Paediatrics: For children a reduced dose based on bodyweight and surface area should be used. The dosage should be calculated for each patient individually and modified in accordance with the physician's experience and knowledge of the patient.

Geriatrics: A reduction in dosage may be necessary for elderly patients especially those with compromised cardiovascular and/or hepatic function. Where epidural administration is to be used, a small dose may provide sufficient anaesthesia.

Impaired hepatic function: Although bupivacaine is metabolised by the liver, dosage reduction is probably not warranted. However, caution should be exercised with repeated doses.

Impaired renal function: Impairment of renal function is unlikely to affect bupivacaine clearance in the short term (up to 24 hours). However, toxicity due to accumulation may develop with prolonged or repeated administration.

Drug Interaction: Bupivacaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. certain anti-arrhythmics, 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 should be advised.

Pharmaceutical Precaution: Keep in a cool & dry place, protected from light. Keep out of the reach of children.

Commercial Pack: Nerkein® Injection: Each box contains 1 vial of 30 ml of Sterile Solution for Injection. Each ml contains Bupivacaine Hydrochloride USP 5 mg.