

PRESCRIBING INFORMATION

SENSOCAIN SPINAL® Injection

(Bupivacaine HCl in Dextrose Injection USP)

STERILE HYPERBARIC SOLUTION FOR SPINAL BLOCK

سینسوکاین اسپائنل
انجکشن

COMPOSITION:

Sensocain Spinal Injection

Each ml Contains:

Bupivacaine Hydrochloride USP.....7.5 mg

Dextrose Anhydrous USP.....82.5 mg

Sensocain Spinal 0.5% Injection

Each ml Contains:

Bupivacaine Hydrochloride USP.....5 mg

Dextrose Anhydrous USP.....80 mg

DESCRIPTION:

Sensocain Spinal (Bupivacaine Hydrochloride in Dextrose Injection USP) is available in sterile hyperbaric Injection for spinal block. Sensocain Spinal (Bupivacaine Hydrochloride in Dextrose Injection USP) is related chemically and pharmacologically to the aminoacyl local anaesthetics. It is a homologue of Mepivacaine and is chemically related to lidocaine.

INDICATIONS AND USAGE:

Sensocain Spinal (Bupivacaine Hydrochloride 0.75 % with Dextrose Injection) and Sensocain Spinal (Bupivacaine Hydrochloride 0.5 % with Dextrose Injection Heavy) is indicated for the production of local and regional Anaesthesia or Analgesia and for subarachnoid block (Spinal Anaesthesia).

DOSAGE AND ADMINISTRATION:

The dose of any local anaesthetic administered varies with the anaesthetic procedure, the area to be anaesthetized, the vascularity of the tissues, the number of neural segments to be blocked, the depth of anaesthesia and degree of muscle relaxation required, the duration of anaesthesia desired, individual tolerance and the physical condition of the patient. The smallest dose and concentration required to produce the desired result should be administered.

The extent and degree of spinal anaesthesia depend upon several factors including dosage, specific gravity of the anaesthetic solution, volume of solution used, force of injection, level of injection, level of puncture and position of patient during and immediately after injection.

Sensocain Spinal (0.75% and 0.5%) Injection has generally proven satisfactory for spinal anaesthesia of lower extremity and perineal procedures including TURP and vaginal hysterectomy. Sensocain Spinal has been used for lower abdominal procedures such as abdominal hysterectomy, tubal ligation and appendectomy.

Sensocain Spinal produces complete motor and sensory block. Unused portions of solutions should be discarded following initial use. Sensocain Spinal injections (0.75% and 0.5%) should be inspected visually for discoloration and particulate matter prior to administration.

CONTRAINDICATIONS:

Sensocain Spinal is contraindicated in patients with a known hypersensitivity to it or to any local anaesthetic agent. The following conditions preclude the use of Spinal Anaesthesia:

- Severe hemorrhage, severe hypotension or shock and arrhythmias, such as complete heart block, which severely restrict cardiac output.
- Local infection at the site of proposed lumbar puncture.
- Septicemia.

WARNINGS:

Local anaesthesia should only be employed by clinicians who are well versed in management of dose related toxicity and other acute emergencies under ventilation from any cause and / or altered sensitivity may lead to the development of acidosis, cardiac arrest, and possibly death. Spinal anaesthetics should not be injected during uterine contractions (labour). A free flow of cerebrospinal fluid during the performance of spinal anaesthesia is indicative of entry into the subarachnoid space.

PRECAUTIONS:

The safety and effectiveness of spinal anaesthetics depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. The patient should have IV fluid running via an indwelling catheter to assure a functioning intravenous pathway. The lowest dosage of local anaesthetic that results in effective anaesthesia should be used. Injection should be pushed slowly. Tolerance varies with the status of the patient. Elderly patients and acutely ill patients may require reduced doses. Reduced doses may also be indicated to patients with increased intra-abdominal pressure (including obstetrical patients), if otherwise suitable for spinal anaesthesia. Careful monitoring of cardiovascular and respiratory after local anaesthetic injection. Restlessness, anxiety, incoherent speech, light headedness, numbness systems and tingling of the mouth and lips, metallic taste, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness may be early warning signs of central nervous system toxicity. Spinal anaesthetics should be used with the caution in patients with severe disturbances of cardiac rhythm, shock or heart block.

Local Anaesthetics should also be used with caution in patients with impaired cardio-vascular function because they may be less able to compensate for functional changes associated with the prolongation of A-V conduction produced by these drugs.

The following conditions may preclude the use of spinal anaesthesia, depending upon the physician's evaluation of the situation and ability to deal with the complaints which may occur:

- Pre-existing diseases of the central nervous system, such as those attributable to pernicious anaemia, poliomyelitis, syphilis or tumor.
- Hematological disorders predisposing to coagulopathies or patients on anticoagulant therapy. Trauma to blood vessels during the conduct of spinal anaesthesia may, in some instances, result in uncontrollable central nervous system hemorrhage or soft tissue haemorrhage.
- Chronic backache and pre-operative headache.
- Hypotension and hypertension.
- Technical problems (persistent paresthesia, persistent bloody tap).
- Extremes of age.
- Psychosis or other causes of poor co-operation by the patient.

STORAGE:

Store at temperature 15-30 °C away from light.

PRESENTATION:

SENSOCAIN SPINAL Injection
Box of 5 X 2ml ampoules

SENSOCAIN SPINAL 0.5% Injection (Heavy)
Box of 5 X 4ml ampoules

خوراک اور طریقہ استعمال:

سینوکین اسپینل انجکشن (0.75% اور 0.5%) سے بیہوشی بذریعہ کمر میں انجکشن کے ذریعے اور اسکی

انتہا کے حصول کے لیے مختصر ترین خوراک دے کر حاصل کی جاسکتی ہے۔

سینوکین اسپینل انجکشن (0.75% اور 0.5%) کے استعمال کے ذریعے جسم کے نچلے حصے کی جراحی قابل عمل ہو جاتی ہے۔

سینوکین اسپینل انجکشن (0.75% اور 0.5%) Vaginal Hysterectomy, Caesarean Section, T. U. R. P

اور کچھ دوسرے جراحی عملیات کے لیے مفید ہے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیں۔

Brookes

Manufactured by:

Brookes Pharma Private Limited
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