1. NAME OF THE MEDICINAL PRODUCT

Sensocain Spinal 0.5% Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Bupivacaine Hydrochloride USP ……5.00mg
Dextrose Anhydrous USP ……..80mg

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Solution for injection
Clear, colorless solution

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

It is indicated for the production of local and reginal Anaesthesia or Analgesia and for subarachnoid block (Spinal Anaesthesia).

4.2 POSOLOGY AND METHOD OF ADMINISTRATION:

The dose of any local anaesthetic administered varies with the anaesthetic procedure, the area to be anaesthesized, 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 0.5% Injection has generally proven satisfactory for spinal anaesthesia of lower extremity and perennial procedures including TURP and vaginal hysterectomy. It 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. It should be inspected visually for discoloration and particulate matter prior to administration.

4.3 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 haemorrhage, 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.
- Septicaemia

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

- 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 performane of spinal anaesthesia is indicative of entry into the subarachnoid space.
- 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 cardiovacular and respiratory after local anaesthetic injection. Restlessness, anxiety, incoherent speech, light headedness, numbness systems ang 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 cardiovascular function because they may be less able to compensate for functional changes associated with the prolonagation 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 tumour.
- Haematological 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 haemorrhage or soft tissue haemorrhage.
- Chronic backache and pre-operative headache.
- Hypotension and hypertension.
- Technical problems (persistent paraesthesia, persistent bloody tap).
- Extremes of age.
- Psychosis or other causes of poor co-operation by the patient.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Bupivacaine should be used with caution in patients receiving other local anesthetics or agents structurally related to amide-type local anesthetics, 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 is advised.

4.6. PREGNANCY AND LACTATION:

There is no evidence of untoward effects in human pregnancy. In large doses, there is evidence of decreased population survival in rats and an embryological effect in rabbits if Sensocain is administered in pregnancy. Sensocain 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. Bupivacaine enters the mother's milk but in such small quantities that there is generally no risk of affecting the child at therapeutic dose levels.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Besides the direct anesthetic effect, local anesthetics may have a very mild effect on mental function and co-ordination even in the absence of overt CNS toxicity and may temporarily impair locomotion and alertness

4.8 ADVERSE EFFECTS:

4.8.1 General

The adverse reaction profile for Sensocain Spinal 0.5% Injection (Heavy) is similar to those for other long acting local anesthetics used for intrathecal Anesthesia.

Table of Adverse Drug Reactions:

Very Common (>1/10)	Cardiac disorders:	Hypotension, bradycardia
	Gastrointestinal disorders:	Nausea
Common (>1/100<1/10)	Nervous system disorders:	Postdural puncture headache
	Gastrointestinal disorders:	Vomiting
	Renal and urinary	Urinary retention, urinary incontinence
Uncommon (>1/1000<1/100)	Nervous system disorders:	Paraesthesia, paresis, dysaesthesia
	Musculoskeletal, connective tissue and bone disorders:	Muscle weakness, back pain
Rare (<1/1000)	Cardiac disorders:	Cardiac arrest
	Immune system disorders:	Allergic reactions, anaphylactic shock
	Nervous system disorders:	Total unintentional spinal block, paraplegia, paralysis, neuropathy, arachnoiditis
	Respiratory disorders:	Respiratory depression

Adverse reactions caused by the drug per se are difficult to distinguish from the physiological effects of the nerve block (e.g. decrease in blood pressure, bradycardia, temporary urinary retention), events caused directly (e.g. spinal haematoma) or indirectly (e.g. meningitis, epidural abscess) by needle puncture or events associated to cerebrospinal leakage (e.g. postdural puncture headache).

4.8.2 Acute systemic toxicity:

Sensocain Spinal 0.5% Injection(Heavy), used as recommended, is not likely to cause blood levels high enough to cause systemic toxicity. However, if other

local anesthetics are concomitantly administered, toxic effects are additive and may cause systemic toxic reactions.

Systemic toxicity is rarely associated with spinal Anesthesia but might occur after accidental intravascular injection. Systemic adverse reactions are characterized by numbness of the tongue, light-headedness, dizziness and tremors, followed by convulsions and cardiovascular disorders.

4.8.3 Treatment of acute systemic toxicity:

No treatment is required for milder symptoms of systemic toxicity but if convulsions occur then it is important to ensure adequate oxygenation and to arrest the convulsions if they last more than 15–30 seconds.

Oxygen should be given by face mask and the respiration assisted or controlled if necessary. Convulsions can be arrested by injection of thiopental 100–150 mg intravenously or with diazepam 5–10 mg intravenously.

Alternatively, succinylcholine 50–100 mg intravenously may be given but only if the clinician has the ability to perform endotracheal intubation and to manage a totally paralyzed patient.

High or total spinal blockade causing respiratory paralysis should be treated by ensuring and maintaining a patent airway and giving oxygen by assisted or controlled ventilation.

Hypotension should be treated by the use of vasopressors, e.g. ephedrine 10–15 mg intravenously and repeated until the desired level of arterial pressure is reached. Intravenous fluids, both electrolytes and colloids, given rapidly can also reverse hypotension.

4.9. OVERDOSE:

Sensocain Spinal 0.5% Injection (Heavy), used as recommended, is not likely to cause blood levels high enough to cause systemic toxicity. However, if other local anesthetics are concomitantly administered, toxic effects are additive and may cause systemic toxic reactions. (See section 4.8.2 and 4.8.3).

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: local Anesthetic Agent.
Bupivacaine is a long acting local anesthetic agent of the amide type.
Moderate muscular relaxation of lower extremities. Motor blockade of the abdominal muscles Sensocain Spinal 0.5% Injection (Heavy) is hyperbaric and its initial spread in the intrathecal space is affected by gravity.

5.2 Pharmacokinetic Properties

Rapid onset of action and long duration i.e. T10–T12 segments – duration 2–3 hours.
Muscular relaxation of lower extremities lasts 2–2.5 hours.

Blockade of the abdominal muscles lasts 45–60 minutes. The duration of motor blockade does not exceed duration of analgesia.

5.3 Preclinical Safety Data:

Bupivacaine Hydrochloride is a well-established active ingredient.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS:

Water for Injection

6.2 INCOMPATIBILITIES:

None Known

6.3 SHELF LIFE:

02 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE:

Store at temperature below 30°C away from light.

6.5 NATURE AND CONTENTS OF CONTAINER:

4ml sterile amber colored glass ampoules in plastic tray packed in carton.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING:

The solution should be used immediately after opening of the ampoule.
Any remaining solution should be discarded

7. Marketing authorizations holder

Brookes Pharma Private Limited
58-59, Sector No. 15, Korangi Industrial Area, Karachi-74900,Pakistan

8. Marketing authorization number

057745

9. Date of first authorisation/renewal of the authorisation

First Authorization: **15-06-2009**

Renewal of Authorization: **15-06-2019**

10. Date of revision of the text

30-04-18