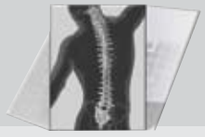

Anespine®

Bupivacaine Hydrochloride USP & Dextrose USP

COMPOSITION

Anespine® Intraspinal Injection: Each ml contains Bupivacaine Hydrochloride USP 5 mg & Dextrose USP 80 mg.

PHARMACOLOGY

Anespine® is a clear, colorless, preservative free sterile hyperbaric solution containing Bupivacaine Hydrochloride and Dextrose.

Bupivacaine is a long-acting local anesthetic agent of the amide type. It has rapid onset of action and long duration. The duration of analgesia in the T10-T12 segments is 2-3 hours.

Bupivacaine produces a moderate muscular relaxation of the lower extremities lasting 2-2.5 hours.

The motor blockade of the abdominal muscles makes the solution suitable for performance of abdominal surgery lasting 45-60 minutes. The duration of motor blockade does not exceed the duration of analgesia.

The cardiovascular effects of **Anespine®** are similar or less than those seen with other spinal agents. Bupivacaine 5 mg/ml with Glucose 80 mg/ml is exceptionally well tolerated by all tissues with which it comes in contact.

INDICATION

Anespine® Injection is indicated for spinal anesthesia in-

- Urological surgery (lasting 2-3 hours)
- Lower limb surgery (lasting 2-3 hours)
- Abdominal surgery (lasting 45-60 minutes)

DOSAGE AND ADMINISTRATION

The doses recommended below should be regarded as a guide for use in the average adult.

Spinal anesthesia for surgery: 2-4 ml (10-20 mg Bupivacaine Hydrochloride). The spread of anesthesia obtained with **Anespine®** depends on several factors including the volume of solution and the position of the patient during and following the injection. When injected in the L3-L4 intervertebral space with the patient in the sitting position, 3 ml of **Anespine®** spreads 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 anesthesia achieved with any local anesthetic can be unpredictable in a given patient.

The effects of Bupivacaine exceeding 4 ml have not yet been studied and such volumes can therefore not be recommended.

SIDE EFFECT

The safety of Bupivacaine is comparable to that of other local anesthetics used for spinal anesthesia. In rare cases Bupivacaine has been associated with allergic reactions and anaphylactic shock. Spinal anesthesia itself can cause hypotension and bradycardia due to sympathetic blockade and/or vasovagal fainting. In severe cases cardiac arrest can occur. High spinal anesthesia may result in paralysis of all respiratory muscles. Postoperatively a post lumbar puncture headache can occur. Neurological damage is a rare but well recognised consequence of regional and particularly spinal anesthesia.
Systemic toxicity: Rarely associated with spinal anaesthesia but might occur after accidental intravascular injection.
Systemic adverse reactions are characterized by numbness of the tongue, lightheadedness, dizziness and tremors, followed by convulsions and cardiovascular disorders.

Treatment of side effects

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 vasopressor, 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.

Treatment of 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 Thiopentone 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 paralysed patient.

PRECAUTION

Spinal anesthesia should only be undertaken by clinicians with the necessary knowledge and experience. Oxygen, other resuscitative drugs, cardiopulmonary resuscitative equipment, and the personnel resources should be immediately available and the anesthetist should remain in constant attendance. Spinal anesthesia with any local anesthetic can cause hypotension and bradycardia which should be anticipated and appropriate precautions should be taken. These may include pre-loading 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 hypovolemia due to hemorrhage or dehydration, or aorto-caval occlusion in patients with massive ascites, large abdominal tumors or late pregnancy. Marked hypotension should be avoided in patients with cardiac decompensation.

Patients with hypovolemia due to any cause can develop sudden and severe hypotension during spinal anesthesia. Spinal anesthesia can cause intercostal paralysis and patients with pleural effusions may suffer respiratory embarrassment. Septicemia can increase the risk of intraspinal abscess formation in the post-operative period.

CONTRAINDICATION

It is contraindicated in patients with a known hypersensitivity to it or to any local anaesthetic agent of the amide type. These conditions preclude the use of spinal anesthesia: 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.

DRUG INTERACTION

Bupivacaine should be used with care in patients receiving antiarrhythmic drugs with local anesthetic activity, as their toxic effects may be additive.

USE IN PREGNANCY AND LACTATION

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.

There is no evidence of untoward effects in human pregnancy. The injection should not be given in early pregnancy unless the benefits are considered to outweigh the risks.

USE IN CHILDREN

Until further experience is gained in patients younger than 18 years, administration of **Anespine®** in this age group is not recommended.

PHARMACEUTICAL PRECAUTION

The solution must not be stored in contact with metals, e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection. The solution should be used immediately after opening of the ampoule. Any remaining solution should be discarded.

STORAGE CONDITION

Store in a cool & dry place, protected from light.

HOW SUPPLIED

Anespine® Intraspinal Injection: Each box contains 10 ampoules in blister pack.

Manufactured by :

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

Revision No.: 00