

For the use of a Registered Medical Practitioner OR A Hospital OR A Laboratory.

(Combi Pack of Lignocaine Injection I.P., 2% w/v 10ml and Bupivacaine Injection I.P., 0.5%w/v 20ml)

AMERICAN

NumbOn-B Combi

Each ml (Part A) contains: Lignocaine HCl I.P. 20mg Sodium Chloride I.P. 6mg Methyl Paraben I.P. 1mg (As Preservative) Water for Injection I.P. q.s.	Each ml (Part B) contains: Bupivacaine HCl I.P. 5mg Sodium Chloride I.P. 8mg Methyl Paraben I.P. 1mg (As Preservative) Water for Injection I.P. q.s
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Therapeutic Category:

Local Anaesthetic and Antiarrhythmic

Description:

Lignocaine HCl Inj I.P. and Bupivacaine HCl Inj I.P. are sterile clear colourless solutions filled in clear glass vials. They produce loss of feeling or sensation confined to one part of the body (local anaesthesia). Both belong to a group of medicines called amide-type local anaesthetics.

Clinical Pharmacology:

Lignocaine and Bupivacaine act by stabilizing the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of impulses, thereby effecting local anaesthetic action. In particular, these agent acts on sodium ion channels located on the internal surface of nerve cell membranes. At these channels, neutral uncharged drug molecules diffuse through neural sheaths into the axoplasm where they are subsequently ionized by joining with hydrogen ions. The resultant drug cations are then capable of reversibly binding the sodium channels from the inside, keeping them locked in an open state that prevents nerve depolarization. As a result, with sufficient blockage, the membrane of the postsynaptic neuron will ultimately not depolarize and will thus fail to transmit an action potential. This facilitates an anaesthetic effect by not merely preventing pain signals from propagating to the brain but by aborting their generation in the first place. In addition to blocking conduction in nerve axons in the peripheral nervous system, these drugs have important effects on the central nervous system and cardiovascular system. After absorption, they may cause stimulation of the CNS followed by depression and in the cardiovascular system; acting primarily on the myocardium where they may produce decreases in electrical excitability, conduction rate, and force of contraction.

Indications: Lignocaine Inj I.P. and Bupivacaine Inj I.P. may be used to produce local anaesthesia by injection of the solution into or around a peripheral nerve or network of nerves, in children and adults. The dosage should be adjusted according to the response of the patient and the site of administration and with precautions in children and elderly.

Contraindications:

Glucose-6-phosphate dehydrogenase (G6PD) deficiency, low amount of potassium in the blood, methemoglobinemia, myasthenia gravis, partial heart block, Wolff-Parkinson-White syndrome, severe heart block, Adams-Stokes syndrome, atrial fibrillation, sinus bradycardia, chronic heart failure, decreased lung function, liver problems, decreased oxygen in the tissues or blood, decreased blood volume, anaemia from pyruvate kinase and G6PD deficiencies, systemic lignocaine toxicity, chronic kidney disease stage 4 (severe).

Precautions:

These medicines may cause a rare, but serious blood problem called methemoglobinemia. The risk may be increased in children younger than 6 months of age, elderly patients, or patients with certain inborn defects. It is more likely to occur in patients receiving too much of the medicine, but can also occur with small amounts. Proceed with caution/Avoid in patients with the following:

Pregnant, likely to be pregnant, or breast feeding epilepsy, heart disease, breathing problems or a disease of the liver or kidneys inflammation or an infection of the skin with pus at or near the site to be injected

Adverse Effects:

Lignocaine and Bupivacaine are generally well tolerated. Like other amide-type local anaesthetics, they may occasionally cause unwanted effects. Only in rare cases have amide-type local anaesthetics been associated with allergic reactions (such as a skin rash, shortness of breath or fall in blood pressure). Serious side effects are rare, but may occur in case of an over dosage or if the solution is rapidly absorbed from the injection site or if it is accidentally injected into a blood vessel. In these circumstances symptoms such as nervousness, dizziness, buzzing in the ears, blurred vision, shakiness, twitching, and drowsiness, feeling breathless or feeling faint may occur.
Dosage: As directed by the Physician.

Overdosage:

Symptoms of overdose and/or acute systemic toxicity involves central nervous system toxicity that presents with symptoms of increasing severity. Patients may present initially with numbness of the tongue, light-headedness, hyperacusis, and tinnitus. Visual disturbance and muscular tremors or muscle twitching are more serious and precede the onset of generalized convulsions. These signs must not be mistaken for neurotic behaviour. Unconsciousness and grand mal convulsions may follow, which may last from a few seconds to several minutes. Hypoxia and hypercapnia occur rapidly following convulsions due to increased muscular activity, together with the interference with normal respiration and loss of the airway. In severe cases, apnoea may occur. Effects on the cardiovascular system may be seen in severe cases. Hypotension, bradycardia, arrhythmia and cardiac arrest may occur as a result of high systemic concentrations, with potentially fatal outcomes.

Metabolism:

Lignocaine and Bupivacaine are metabolized predominantly and rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. The pharmacological/toxicological actions of these metabolites are similar to, but less potent than, those of Lignocaine HCl and Bupivacaine HCl. Approximately 90% of Lignocaine HCl and 94% of Bupivacaine HCl administered are excreted in the form of various metabolites, and less than 10% and 6% are excreted unchanged.

Storage:

Store in a cool place, Away from direct sunlight.

Caution:

Please do not use if any vial contains particles or suspended matter.

Package Information:

Lignocan-B Combi is presented as a combi pack containing one vial each of Lignocaine HCl Injection I.P., 10ml and Bupivacaine Injection I.P., 20ml in plastic thermoform trays with printed outer box.

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