SCHEDULING STATUS: **S4**

PROPRIETARY NAME (and dosage form): **ADCO-BUPIVACAINE HCl 0,5% Injection**

COMPOSITION:

Each 1 ml contains Bupivacaine Hydrochloride 5 mg.

PHARMACOLOGICAL CLASSIFICATION:

A.4 Local anaesthetics

PHARMACOLOGICAL ACTION:

Bupivacaine Hydrochloride is a long-acting local anaesthetic of the amide type. Bupivacaine prevents the generation and conduction of nerve impulses thereby effecting local anaesthesia. Bupivacaine is not detoxified by plasma esterases.

INDICATIONS:

Peripheral nerve block, epidural and caudal block.

CONTRA-INDICATIONS:

Bupivacaine Hydrochloride is contra-indicated in patients who are sensitive to it or to anaesthetics of the amide type.

Bupivacaine is not recommended for use in intravenous regional anaesthesia or paracervical block in obstetrics. Epidural techniques should not be employed in patients with cerebrospinal disease.

The safety of Bupivacaine in pregnancy, other than in labour has not yet been established.

ADCO-BUPIVACAINE HCl 0,5% is not recommended for use in children younger than 12 years.

WARNINGS:

Resuscitation equipment, such as equipment to maintain a free airway, oxygenation and circulation should be immediately available when administering Bupivacaine.

DOSAGE AND DIRECTIONS FOR USE:

The onset of action and depth of anaesthesia depends upon the concentration, dose and route of administration.

The dose of Bupivacaine should be reduced in the elderly, in children and in debilitated patients, and in cardiac or hepatic disease.

The following doses are recommended as a guide for adults.

PROCEDURE	DOSE		REMARKS
	ml	mg	
Peripheral Nerve Block	5 ml	25 mg	May be increased to 150 - 175 mg (30 - 35 ml) as a single dose or 400mg per day.
Lumbar epidural	10-20 ml	50 – 100 mg	

Block			Doses may be repeated, at intervals no shorter than 3 hours to a maximum of 400 mg daily.
Caudal Block	5 – 30 ml	25 – 150 mg	

It is recommended that a test dose is given before commencing epidural block and that subsequent doses are given in small increments. Single doses should not exceed 150 mg to 175 mg and no more than 400 mg should be given daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Adverse events may occur due to the addition of vasoconstrictors. The systemic toxicity of local anaesthetics mainly involves the central nervous system and the cardiovascular system.

Excitation of the central nervous system may be manifested by restlessness, excitement, dizziness, nervousness, tinnitus, blurred vision, nausea and vomiting, muscle twitching and tremors, and convulsions, numbness of the tongue and perioral region may appear as an early sign of systemic toxicity. Excitation may be followed by depression with drowsiness, respiratory failure, and coma. There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia; arrhythmias and cardiac arrest may occur. Methaemoglobinaemia may occur.

Foetal intoxication has occurred following the use of local anaesthetics in labour; either as a result of the transplacental diffusion or after accidental injection of the foetus.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See Side-effects and Special Precautions.

Treatment is symptomatic and supportive. The circulation must be maintained and convulsions must be controlled. A patent airway must be established and oxygen given, together with assisted ventilation if necessary. The circulation should be maintained with infusions of plasma or intravenous fluids.

IDENTIFICATION:

A clear colourless solution.

PRESENTATION:

10 ml ampoules in packs of 10 ampoules.

STORAGE INSTRUCTIONS:

Store below 25 °C. Protect from light. Keep out of reach of children.

REGISTRATION NUMBER:

Z/4/63

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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