1.3.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S4**

PROPRIETARY NAME: **MACAINE® HCl 0,5 % INJECTION**

(AND DOSAGE FORM) **INJECTION**

COMPOSITION:

Each 1 ml sterile aqueous solution contains:

MACAINE®, brand of bupivacaine (1-Butyl-2',6'-pipecoloxylidide) hydrochloride 5 mg

Excipient: Sodium chloride

Sugar free

CATEGORY AND CLASS:

A.4 Local anaesthetics

PHARMACOLOGICAL ACTION:

Administration of **MACAINE®** stabilizes the neuronal membrane and prevents initiation and transmission of nerve impulses, thereby effecting local anaesthetic action. The onset of action is rapid and anaesthesia may last several hours. The duration of action is significantly longer with **MACAINE®** than with any other commonly used local anaesthetic.

Because of its amide structure, **MACAINE®** is not detoxified by plasma esterases. When administered in recommended doses and concentration, it does not ordinarily produce irritation or tissue damage and does not cause methaemoglobinaemia.

INDICATIONS:

Peripheral nerve block, caudal or epidural block.

CONTRA-INDICATIONS:

MACAINE® is contra-indicated in patients with known sensitivity to any of its ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

Safe use of **MACAINE®** in pregnant women, other than those in labour, has not been established. Foetal bradycardia frequently follows paracervical block with some amide-type local anaesthetics and may be associated with foetal acidosis.

Added risk appears to be present in prematurity, toxaemia of pregnancy and foetal distress. Until further clinical experience is gained paracervical block with **MACAINE®** is not recommended.

RESUSCITATIVE EQUIPMENT AND DRUGS SHOULD BE READILY AVAILABLE WHEN ANY LOCAL ANAESTHETIC IS USED.

Caution is advised in administration of repeat doses of **MACAINE® 0,5 % INJECTION** to patients with severe liver disease.

Check for minute leaks by squeezing.

Do not use if solution is brown or contains a precipitate. Discard unused portion after initial use.

INTERACTIONS:

Interaction studies have not been performed.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Dosage varies and depends upon the area to be anaesthetized, the vascularity of the tissues, the number of neuronal segments to be blocked, individual tolerance and technique of anaesthesia.

In recommended doses, **MACAINE®** produces complete sensory block, but the effect on motor function differs depending on volume utilized. The duration of anaesthesia is such that for most indications, a single dose is sufficient

The dosages of **MACAINE® 0,5% INJECTION** in the table below have generally proved satisfactory and are recommended as a guide for use in the average adult. Until further experience is gained, **MACAINE®** is not recommended for children younger than 12 years.

Procedure	**Dose**		**Remarks**
	ml	**mg**	
Trigeminal block	0,5 - 4	2,5 – 20	
Axillary block	15 - 30	75 - 150	
Intercostal block	3 - 5	15 - 25	The dose indicated is for every segment.
Epidural Anaesthesia	10 - 20	50 - 100	
Continuous epidural Anaesthesia	Initially 10 ml followed by 3 – 5 – 8 ml every 4 – 6 hours. The dose depends on the number of segments to be rendered analgesic and the patient's age.		
Caudal anaesthesia	15 - 30	75 - 150	

The maximum recommended dose of **MACAINE®** in a single injection 1s 150 mg and should not be exceeded unless there are special considerations present. Where dosage is calculated on the patient's mass, this should not exceed 2 mg/kg body mass up to a maximum of 150 mg.

SIDE EFFECTS:

Reactions to **MACAINE®** are characteristic of those associated with other amide-type local anaesthetics. High plasma levels caused by excessive dosage, inadvertent intravascular injection or slow metabolic degradation cause systemic reactions involving the central nervous system and the cardiovascular system.

CNS effects:

Excitation or depression. The first manifestation may be nervousness, dizziness, blurred vision or tremors, followed by drowsiness, sometimes merging into unconsciousness and respiratory arrest. Other effects may be nausea, vomiting, chills, constriction of the pupils or tinnitus

CVS effects:

Depression of the myocardium blood pressure changes (usually hypotension), and cardiac arrest.

Allergic effects are characterized by cutaneous lesions (e.g, urticaria), oedema and other manifestations of allergy. Detection of sensitivity by skin testing is of doubtful value.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:

Toxic effects of local anaesthetics require symptomatic treatment; there is no specific cure.
The physician should be prepared to maintain an airway and to support ventilation with oxygen.
Supportive treatment of the cardiovascular system includes intravenous fluids and when appropriate, vasopressors Convulsions may be controlled with oxygen and intravenous administration of diazepam or short-acting barbiturates.

IDENTIFICATION:

Clear, colourless, sterile, aqueous solution.

PRESENTATION:

10 ml Glass or plastic ampoules in packs of 10.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light.

Discard unused portion after initial use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

J/4/113

NA: NS2 90/4/00133

BW: S2 B9300545

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg, 2013

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

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