SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

SCANDONEST 3% PLAIN
BIOCAINE 3% PLAIN, solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mepivacaine hydrochloride 30.00 mg per ml

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Local anaesthesia in dental and chiropody procedures.

4.2 Posology and method of administration

Method of administration:
Local injection (infiltration or nerve block).

Posology in dentistry:

Adults:
1 cartridge for routine work.
Do not exceed 3 cartridges.

Children:
Age 6 to 14 years: Usual dose 1.6 ml. Do not exceed 3.3 ml.
Age 3 to 6 years: 1.1 ml to 2.2 ml.
Do not use under 3 years of age.

Posology in chiropody:

Adults:
2.2 to 4 ml.
Use no more than 4.4 ml per digit. Do not exceed 6 mg per kg of body weight per 24 hours.

4.3 Contraindications

SCANDONEST 3% PLAIN should not be used in patients presenting specific allergies to amide type anaesthetics.

4.4 Special warnings and precautions for use

Practitioners who employ local anaesthetic agents should be well versed in diagnosis and management of emergencies which may arise from their use. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use.

- Do not inject into a blood vessel - inject slowly:
  To minimize the likelihood of intravascular injection, aspiration should be performed before the local anaesthetic solution is injected. If blood is aspirated, the needle must be repositioned until no return of blood can be elicited by aspiration. Note, however, that the absence of blood in the syringe does not assure that intravascular injection will be avoided and a double aspiration is always recommended.

- Local anaesthetic procedures should be used with caution when there is inflammation and/or sepsis in the region of the proposed injection.

- This product does not contain any preservatives.

- Use of the cartridge:
  Use on one patient during one session of treatment only. If only part is used, the remainder must be discarded.

- <u>General precautions</u>

The safety and effectiveness of mepivacaine depend on proper dosage, correct technique, adequate precautions and readiness for emergencies. Resuscitative equipment, oxygen and other resuscitative drugs should be available for immediate use.

The lowest dosage that results in effective anaesthesia should be used to avoid high levels and serious adverse effects. Repeated doses of mepivacaine may cause significant increases in blood levels with each repeat dose due to slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical condition (see Posology and method of administration).

Cardiovascular and respiratory (adequacy of ventilation) vital signs and the patient's state of consciousness should be monitored after each local anaesthetic injection. Restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness should alert the practitioner to the possibility of central nervous system toxicity. Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position: placing the patient in the recumbent position is recommended when an adverse response is noted after injection of a local anaesthetic. (See Undesirable effects: cardiovascular system).

- Mepivacaine should be used with caution in:

- Patients with hepatic disease, since amide-type local anaesthetics are metabolized by the liver. Patients with severe hepatic disease, because of their inability to metabolize local anaesthetics normally, are at greater risk of developing toxic plasma concentrations.
- Patients with renal disease, since local anaesthetics are excreted by the kidneys, and the patient due to his condition is also at a greater risk of developing toxic plasma concentrations.

- The use of mepivacaine should be carefully considered if:

- There is inflammation and/or sepsis in the region of injection, since this may alter the pH at the site of injection, resulting in decrease or loss of anaesthetic effect.
- There is a history of severe disturbances of cardiac rhythm or heart block, since the cardiac depressant effects of the anaesthetic are detrimental to the patient.

4.5 Interactions with other medicinal products and other forms of interaction

Interactions with other medicaments:
If sedatives are employed to reduce patient apprehension, reduced doses of anaesthetic solution should be used since local anaesthetic agents, like sedatives, are central nervous system depressants which in combination may have an additive effect.

4.6 Pregnancy and lactation

In pregnancy

On the basis of long usage, anaesthetics of the mepivacaine type are considered to be reasonably safe for use on pregnant women.
Retrospective studies of pregnant women receiving local anaesthetics for emergency surgery early in pregnancy have not shown that local anaesthetics cause birth defects.
However, no controlled studies have been carried out in pregnant women.
Moreover, no animal reproduction studies have been performed with mepivacaine. Therefore, caution should be taken before administering this anaesthetic during early pregnancy.

Nursing mothers

It is not known whether local anaesthetics are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when mepivacaine is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse experiences following the administration of mepivacaine are similar in nature to those observed with other amide local anaesthetic agents. These

adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage, rapid absorption or unintended intra-vascular injection, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature.

The following types are those most commonly reported:

- **Central Nervous System**

CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, blurred or double vision, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of mepivacaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

- **Cardiovascular system**

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position. Less commonly, they may result from a direct effect of the drug. Failure to recognize the premonitory signs such as sweating, a feeling of faintness, changes in pulse or sensorium may result in progressive cerebral hypoxia and seizure or serious cardiovascular catastrophe. Management consists of placing the patient in the recumbent position and ventilation with oxygen. Supportive treatment of circulatory depression may require the administration of intravenous fluids, and when appropriate, a vasopressor (e.g. ephedrine) as directed by the clinical situation.

- **Allergic reactions**

Allergic reactions are characterized by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Allergic reactions as a result of sensitivity to mepivacaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

4.9 Overdose

Acute emergencies from local anaesthetics are generally related to high plasma levels encountered during therapeutic use of excessive dosage of local anaesthetics, or to unintended intravascular injection of local anaesthetic solution. (See Undesirable effects, Special warnings and precautions for use).

- **Management of local anaesthetic emergencies:**

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anaesthetic injection. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions consists of immediate attention to the maintenance of a patent airway and assisted and controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask.

Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamylal) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anaesthetics, with these anticonvulsant drugs. Supportive treatment of circulation depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrythmias and cardiac arrest. If cardiac arrest should occur, standard cardio-pulmonary resuscitative measures should be instituted.

Endotracheal intubation, employing drugs and techniques familiar to the clinician, may be indicated, after initial administration of oxygen by mask, if difficulty is encountered in the maintenance of a patent airway or if prolonged ventilatory support (assisted or controlled) is indicated.

Dialysis is of negligible value in the treatment of acute overdosage with mepivacaine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: local anaesthesics
ATC code: N01BB03

Mepivacaine stabilizes the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting local anaesthesia.

Unlike procaine and lignocaine, mepivacaine is characterized by a lack of intrinsic vessel dilation activity which makes possible the use of this anaesthetic, for dental procedures of comparatively short duration, without the addition of a vasocontrictor.

- Dental procedures:

The onset of action is rapid, 30 to 120 seconds in the upper jaw; 1 to 4 minutes in the lower jaw.
SCANDONEST 3% PLAIN will ordinarily provide an operative anaesthesia of 20 minutes in the upper jaw and 40 minutes in the lower jaw.

- Chiropody:

The onset of action is between 4 and 8 minutes.
SCANDONEST 3% PLAIN will ordinarily provide an operating anaesthesia of about 1 hour.

5.2 Pharmacokinetic properties

Information derived from diverse formulations, concentrations and usages reveals that systemic absorption of mepivacaine is complete following parenteral administration, its rate of absorption depending upon various factors, such as the site of injection and the presence or absence of a vasoconstrictor agent.

Mepivacaine is rapidly metabolized. The liver is the principal site of metabolism, with over 50 per cent of the administered dose being excreted into the bile as metabolites. Most of the metabolized mepivacaine is probably resorbed in the intestine and then excreted into the urine, since only a small percentage is found in the feces. The principal route of excretion is via the kidneys. Most of the anaesthetic and its metabolites are eliminated within 30 hours.

A percentage of up to 16 per cent of the dose administered is excreted unchanged in the urine.

It has been shown that hydroxylation and N-demethylation, which are detoxification reactions, play important roles in the metabolism of the anaesthetic. These metabolites of mepivacaine have been identified from adult humans: two phenols, which are excreted almost exclusively as their glucuronide conjugates, and the N-demethylated compound (2', 6'-pipecoloxylidide).

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, sodium hydroxide solution and water for injections.

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

The product is to be stored below 25ºC.

To prevent from light and to aid stability, each time cartridges are taken remember to replace the blister into the carton and close this latter.

6.5 Nature and contents of container

- Glass cartridges with rubber closures.
- 50 dental cartridges of 1.8 ml or 2.2 ml in blister packs grouped in a cardboard box.

6.6 Special precautions for disposal

See 4.4 "Special warnings and precautions for use"

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 08313/0023

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/11/1987 – 02/11/1992 – 22/06/1999

10. DATE OF REVISION OF THE TEXT

February 2004.