

Scandonest 3% Plain

Solution for injection

POM

Qualitative and quantitative composition

Mepivacaine hydrochloride 30.00 mg per ml.
For excipients, see "List of excipients".

Pharmaceutical form

Solution for Injection

Therapeutic indications

Local anaesthesia in dental and chiropody procedures.

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

Pediatric population:

Children from 4 years of age (ca. 20 kg body weight) and older (see 4.3.)

Recommended therapeutic dose:

The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. The average dosage is 0.75 mg/kg = 0.025 ml of mepivacaine solution per kg body weight.

Maximum recommended dosage:

Do not exceed the equivalent of 3 mg mepivacaine/kg (0.1 ml mepivacaine/kg) of body weight.

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.

Contraindications

Scandonest 3% Plain should not be used:

- in children below 4 years of age (ca. 20 kg body weight)
- in patients presenting specific allergies to amide type anaesthetics.

Special warnings and special 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.
- General precautions :

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 repeated 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.

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.

Pregnancy and lactation

- Pregnancy

On the basis of long usage, anaesthetics of the mepivacaine type are considered to be reasonably safe for use in 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.

Effect on ability to drive and use machines

None reported.

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

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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, edema 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.

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, arrhythmias 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.

Pharmacodynamic properties

Pharmacotherapeutic group: local anaesthetics

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 vasoconstrictor.

• 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.

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'-pipecodoxylidide).

List of excipients

Sodium chloride, sodium hydroxide solution, water for injections.

Incompatibilities

Not applicable.

Shelf life

3 years.

Special precautions for storage

The product is to be stored below 25°C.

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.

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.

Instructions for use/handling

See "Special warnings and precautions for use".

Marketing authorisation holder and distributor

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Marketing authorisation number

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Date of revision of the text

February 2011

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2/11/1987 - 2/11/1992 - 22/06/1999

Manufacturer:

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Scandonest 3% Plain

Solution for injection

Mepivacaine hydrochloride

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist.

In this leaflet:

1. What SCANDONEST 3% PLAIN is and what it is used for
2. Before you use SCANDONEST 3% PLAIN
3. How to use SCANDONEST 3% PLAIN
4. Possible side effects
5. How to store SCANDONEST 3% PLAIN
6. Further information

1. What SCANDONEST 3% PLAIN is and what it is used for

SCANDONEST 3% PLAIN is given by injection to cause loss of feeling before and during chiropody and dental procedures. It contains one active ingredient: mepivacaine hydrochloride, a local anaesthetic which prevents the pain.

SCANDONEST 3% PLAIN is for children over 4 years old and adults.

Only a dentist can administer this product.

2. Before you use SCANDONEST 3% PLAIN

Do not use SCANDONEST 3% PLAIN

- if you are allergic (hypersensitive) to the active ingredient (mepivacaine hydrochloride) or to any of the other ingredients (refer to section 6).
- you are allergic to local anaesthetics called amide type anaesthetics,
- in children under 4 years old.

Take special care with SCANDONEST 3% PLAIN

Before receiving this medicine, tell your dentist if:

- you have problems with your heart,
- you have problems with your liver,
- you have problems with your kidneys,
- you have a severe infection or an inflammation in the area where the injection will be done.

Using other medicines

Please tell your dentist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Your dentist should take special attention if you are taking the following medicines:

- medicines used to reduce patient apprehension (e.g. sedatives). In that case, the dosage of anaesthetic should be reduced.

Pregnancy and breast-feeding

This medicine should be used with caution during pregnancy or breast-feeding.

Ask your dentist for advice before taking any medicine.

Driving and using machines

If you experience side effects, including dizziness or blurred vision, you should not drive or operate machinery until these effects have disappeared.

Important information about some ingredients of SCANDONEST 3% PLAIN

SCANDONEST 3% PLAIN contains less than less than 1 mmol (23mg) sodium per cartridge, i.e. essentially "sodium free".

3. How to use SCANDONEST 3% PLAIN

Your dentist will explain to you why you are being treated with SCANDONEST 3% PLAIN. He will choose the formula and adjust the dosage according to your age, your health and the dental procedure.

One cartridge is usually sufficient but your dentist may give you a greater quantity.

SCANDONEST 3% PLAIN is injected between two teeth. It should not be injected into a blood vessel.

If your dentist uses more SCANDONEST 3% PLAIN than he should

If you think you may have been given too much of this injection and feel unwell (see section 4, possible side effects), tell your dentist.



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4. Possible side effects

Like all medicines, SCANDONEST 3% PLAIN, can cause side effects, although not everybody gets them.

While you are in your dentist office, your dentist will carefully follow the effects of SCANDONEST 3% PLAIN.

However, some effects may not be noticed or appear later.

Check with your dentist, doctor or pharmacist if any of the following side effects occur:

- **General effects:** feeling nervous, nausea, vomiting, headache, dizziness, twitching, apprehension, feeling of well-being commonly exaggerated, confusion, drowsiness, malaise, agitation, convulsions, unconsciousness, faint
- **Effects on your senses:** trembling, light headedness, buzzing in the ears, blurred or double vision, sensation of heat, cold or numbness,
- **Effects on your lung:** difficulty in breathing
- **Effects on your heart and blood vessels:** slow heartbeats, low blood pressure,
- **Effects on your skin:** skin rash, hives or itching or severe allergic reaction (including swelling of the face, lips and/or tongue, difficulty in breathing).

You may develop more severe reactions such as convulsions and reduced level of consciousness with possible arrest of breathing or heart. Emergency medical help should immediately be called.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist.

5. How to store SCANDONEST 3% PLAIN

Keep out of the reach and sight of children.

It is most unlikely that you will be asked to look after this medicine.

Your dentist will not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Your dentist will keep it up to 25°C, stored in the original container (protected from light).

6. Further information

What SCANDONEST 3% PLAIN contains

- Active substance: each ml of solution for injection contains 30 mg of mepivacaine hydrochloride.
- The other ingredients are: sodium chloride, sodium hydroxide solution and water for injection.

What SCANDONEST 3% PLAIN looks like and content of the pack

It is a clear and colourless solution for injection.

SCANDONEST 3% PLAIN is available in boxes containing 50 cartridges of 1.8 ml or of 2.2 ml.

Marketing authorisation holder

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If more PILs are necessary, call free number 0800435155.



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