Package leaflet: Information for the user

Scandonest 2% Special, solution for injection
mepivacaine hydrochloride and adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist, doctor or pharmacist.
- If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects listed in this leaflet. See section 4.

This product will be referred to as Scandonest 2% Special from here on.

What is in this leaflet:

1. What Scandonest 2% Special is and what it is used for

Scandonest 2% Special is given by injection to cause loss of feeling before and during dental procedures.
It contains two active ingredients:
- mepivacaine hydrochloride, a local anaesthetic which prevents pain,
- adrenaline, a vasoconstrictor which makes the effect last longer. Adrenaline narrows the blood vessels at the site of injection, which keeps the anaesthetic where needed for a longer time. It also controls the bleeding during the surgery.

Scandonest 2% Special is for children over 4 years old and adults.

Only a dentist can administer this product.

2. What you need to know before you use Scandonest 2% Special

Do not use Scandonest 2% Special
- if you are allergic to mepivacaine hydrochloride or adrenaline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to local anaesthetics
- if you have a high blood pressure (arterial hypertension),
- if you have particular heart or blood vessels disease (coronary or valvular cardiac disease),
- if you are taking or have taken medicines for depression in the last two weeks,
- in children under 4 years old.

Warnings and precautions
Talk to your dentist before using Scandonest 2% Special if:
- you have problems with your heart or blood vessels,
- you have problems with your liver,

- you have problems with your kidneys,
- you have a severe infection or an inflammation in the area to be injected,
- you are epileptic,
- you have troubled breathing.

Other medicines and Scandonest 2% Special
Tell your dentist if you are taking, have recently taken or might take any other medicines. This is especially important with the following medicines, as precautions should be taken by your dentist:
- medicines used to treat some psychotic disorders (phenothiazine antipsychotics)
- heart and blood pressure medicines (vasopressors, beta-adrenergic blocking agents)
- medicines used for migraine attacks (ergot-type oxytoxic drugs)
- medicines used to reduce patient apprehension (e.g. sedatives).
- some anaesthetics that are inhaled (such as chloroform, halothane, cyclopropane, trichloroethylene)
- medicines used to treat depression (monoamine oxydase inhibitors (MAOI) or tricyclic antidepressants)

Pregnancy and breast-feeding
This medicine should be used with caution during pregnancy or breast-feeding.
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist, doctor or pharmacist for advice before using this medicine.

Driving and using machines
Scandonest 2% Special has no or negligible influence on the ability to drive and use machines.

Scandonest 2% Special contains sodium and potassium metabisulfite.
Sodium: less than 1 mmol sodium (23 mg) per cartridge, i.e. essentially "sodium free".
Potassium metabisulfite: it may rarely cause severe hypersensitivity reactions and difficulty in breathing (bronchospasm).
This medicine contains potassium less than 1 mmol (39 mg) per cartridge, i.e. essentially “potassium-free”.

3. How to use Scandonest 2% Special

Your dentist will explain to you why you are being treated with Scandonest 2% Special.
He or she will 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 2% Special is injected between two teeth.

If your dentist used more Scandonest 2% Special than he or she 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. While you are in your dentist’s office, your dentist will carefully follow the effects of Scandonest 2% Special.

Immediately inform your dentist, doctor or pharmacist if you experience one of the following serious side effects:
- Severe allergic reactions (anaphylactoid reactions) characterized by rash, itching, swelling of the face, lips, gums, tongue and/or throat and difficulty breathing. These allergic-type reactions may occur in patients with wheezing asthma (bronchospasm) due to allergy to sulphites (see section “Important information about some ingredients of Scandonest 2% Special)
- Unconsciousness

- Seizures (convulsions)
- Drop in blood pressure (cardiovascular collapse) which may lead to cardiac arrest, rapid and irregular heartbeats (ventricular fibrillation), severe and crushing chest pain (angina pectoris)
- Abnormally slow breathing, respiratory arrest
- Allergic reactions characterized by skin rash (cutaneous lesions), eruption of itching wheals (urticaria), swelling (edema)
- Blurred or double vision

Other side effects not listed above may also occur:

Common: may affect up to 1 in 10 people:

- Abnormally slow heartbeat (bradycardia), palpitations, low or high blood pressure, feeling of well-being commonly exaggerated (euphoria), ; if you are in an upright position, a vasovagal reaction may develop (brief loss of consciousness preceded by sweating, feeling of faintness, changes in pulse), lightheadedness, dizziness, throbbing headache, nervousness, restlessness, confusion, apprehension, increasing fear and anxiety, weakness, paleness, drowsiness, ringing in the ears (tinnitus), vomiting, sensations of heat, cold or numbness, uncontrolled eye movement (twitching), trembling.

Reporting of side effects

If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Scandonest 2% Special

Keep this medicine out of the sight and reach 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. Do not freeze.
Keep the cartridges in the outer carton in order to protect from light.

6. Contents of the pack and further information

What Scandonest 2% Special contains

- The active substances are
  mepivacaine hydrochloride and
  adrenaline base (epinephrine).
- The other ingredients are: potassium metabisulphite (E 224), sodium chloride, disodium edetate, hydrochloric acid, sodium hydroxide and water for injection.

What Scandonest 2% Special looks like and content of the pack

It is a solution for injection.
Scandonest 2% Special is available in boxes containing 50 cartridges of 1.8 ml or 2.2 ml.

Marketing Authorisation Holder
Septodont Limited, Units R & S
Orchard Business Centre
St Barnabas Close
Allington, Maidstone
Kent ME16 0JZ - United Kingdom

Manufacturer
Septodont
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés
France

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The following information is intended for healthcare professionals only:

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

Paediatric 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 = 0.0375 ml of mepivacaine solution per kg body weight.

Maximum recommended dosage:
Do not exceed the equivalent of 3 mg mepivacaine/kg (0.15 ml mepivacaine/kg) of body weight.

Method of administration:
Infiltration or nerve block injection.

Precautions for use
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 dose resulting in effective anaesthesia should be used to avoid high plasma 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).
Patients with peripheral vascular disease may exhibit exaggerated vasoconstrictor response.
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.

Mepivacaine should be used with caution in:
Patients with hepatic disease, since amide-type local anaesthetics are metabolised by the liver. Patients with severe hepatic disease, because of their inability to metabolise local anaesthetics normally, are at greater risk of developing toxic plasma concentration,
Patients with renal disease, since local anaesthetics are excreted by the kidneys. Due to their condition, these patients are at 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 decreased 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.
- Scandonest 2% Special should be administered with caution to subjects with epilepsy and impaired respiratory function.

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 or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask.
Immediately after 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 cardiopulmonary 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.