**Package leaflet: Information for the patient**

# *Scandonest 3% Plain*

Solution for injection

**Mepivacaine hydrochloride**

**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 doctor, dentist or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**


1. What Scandonest 3% Plain is and what it is used for
2. What you need to know 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. Contents of the pack and other information


## 1. What Scandonest 3% Plain is and what it is used for

Scandonest 3% Plain is a local anaesthetic, which numbs a particular region to prevent or minimize pain. The medicine is used in local dental procedures in adults, adolescents and children above 4 years of age (ca. 20 kg in body weight). It contains the active substance mepivacaine hydrochloride and belongs to the group of nervous system anaesthetics.

## 2. What you need to know before you use Scandonest 3% Plain

**Do not use Scandonest 3% Plain:**
- If you are allergic to mepivacaine or any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to other local anaesthetics of the same group (e.g. lidocaine, bupivacaine);
- If you suffer from:
  - Heart disorders due to the abnormality of the electronic impulse triggering the heart beat (severe conduction disturbances);
  - Epilepsy not adequately controlled by treatment;
- In children below 4 years of age (ca. 20 kg in body weight).

**Warnings and precautions**
Talk to your dentist before using Scandonest 3% Plain if you suffer from any of the following conditions:
- heart disorders;
- a severe anaemia;
- high blood pressure (severe or untreated hypertension);
- a low blood pressure (hypotension);
- epilepsy;
- liver disease;
- kidney disease;
- a disease which affects the nervous system and results in neurological disorders (porphyria);
- a high acidity in the blood (acidosis);
- poor blood circulation;
- impairment of your general condition;
- inflammation or infection in the injection site.

If any of these situations applies to you, tell your dentist. He/she may decide to give you reduced dose.

**Other medicines and Scandonest 3% Plain**
Tell your dentist if you are taking, have recently taken or might take any other medicines, particularly:
- other local anaesthetics;
- medicines used to treat heartburn and ulcers of the stomach and intestines (such as cimetidine);
- tranquilizing and sedative medicines;
- medicines used to stabilize heartbeat (antiarrhythmics);
- Cytochrome P450 1A2 inhibitors;
- medicines used to treat hypertension (propranolol).

**Scandonest 3% Plain with food**
Avoid eating, included chewing-gum, until normal sensation is restored because there is a risk that you may bite your lips, cheeks or tongue, especially in children.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, dentist or pharmacist for advice before using this medicine.
As a precautionary measure, it is preferrable to avoid the use of this product during pregnancy, unless necessary.
Nursing mothers are advised not to breastfeed 10 hours following anaesthesia with this product.

**Driving and using machines**
This medicine may have a minor influence on the ability to drive and use machines. Dizziness (including a feeling of “spinning”, vision disorder and fatigue), loss of consciousness may occur following administration of this medicine (see section 4). You should not leave the dental office until you are sure the effects have worn off (generally within 30 minutes) following the dental procedure.

**Scandonest 3% Plain contains sodium**
This medicine contains 24.67 mg sodium per 10 ml (maximum recommended dose). This is equivalent to 1.23 % of the recommended maximum daily dietary intake of sodium for an adult.

## 3. How to use Scandonest 3% Plain

Scandonest 3% Plain should only be used by or under the supervision of dentists, stomatologists or other, trained clinicians by a slow local injection.
They will determine the appropriate dose taking into account the procedure, your age, your weight and your general health.
The lowest dose leading to efficient anaesthesia should be used.
This medicine is given as an injection in the oral cavity.

**If you are given more Scandonest 3% Plain than you should**
The following symptoms may be signs of toxicity due to excessive doses of local anaesthetics: agitation, a sensation of numbness in the lips and tongue, prickling and tingling around the mouth, dizziness, visual and hearing disturbances, and buzzing in the ears, muscle stiffness and twitching, low blood pressure, low or irregular heart rate. If you experience any of these, stop administration and seek medical assistance immediately.

If you have any further questions on the use of this medicine, ask your doctor or dentist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
One or more of the following side effects may occur following administration of Scandonest 3% Plain.

**Common side effects** (may affect up to 1 in 10 people):
- Headache

**Rare side effects** (may affect up to 1 in 1,000 people):
- rash, itching, swelling of the face, lips, gums, tongue and/or throat and difficulty breathing, wheezing/asthma, hives (urticaria): these might be symptoms of hypersensitivity reactions (allergic or allergy-like reactions);
- pain due to nerve damage (neuropathic pain);
- burning sensation, prickling skin sensation, tingling with no apparent physical cause around the mouth (paraesthesia);
- abnormal sensation in and around the mouth (hypoesthesia);
- metallic taste, taste distortion, taste loss (dysesthesia);
- dizziness (lightheadedness);
- tremor;
- loss of consciousness, fit (convulsion), coma;
- fainting;
- confusion, disorientation;
- speech disturbances, excessive talkativeness;
- restlessness, agitation;
- impaired sense of balance (disequilibrium);
- drowsiness;
- vision blurred, problems clearly focusing an object, visual impairment;
- a feeling of spinning (vertigo);
- failure of the heart to contract effectively (cardiac arrest), rapid and erratic heartbeats (ventricular fibrillation), severe and crushing chest pain (angina pectoris);
- heartbeat coordination problems (conduction disorders, atrioventricular block), abnormal slow heartbeat

(bradycardia), abnormal rapid heartbeat (tachycardia), palpitations;
- low blood pressure;
- increase of blood flow (hyperaemia);
- breathing difficulties such as shortness of breath, abnormally slow or very rapid breathing;
- yawning;
- feeling sick, vomiting, mouth or gum ulcers, swelling of tongue, lips or gums;
- excessive sweating;
- muscle twitching;
- chills;
- swelling at the site of injection.

**Very rare side effects** (may affect up to 1 in 10,000 people):
- high blood pressure.

**Not known** (frequency cannot be estimated from the available data):
- euphoric mood, anxiety/nervousness;
- involuntary eye movements, eye problems such as narrowed pupil, falling of the upper eyelid (as in Horner's syndrome), dilated pupil, the posterior displacement of the eyeball within the orbit due to changes in the volume of the orbit (called *Enophthalmos*), doubled vision or vision loss;
- ear disturbances, such as ringing in the ears, oversensitivity of hearing;
- failure of the heart to contract effectively (myocardial depression);
- widening of blood vessels (vasodilatation);
- changes in the colour of your skin with confusion, cough, fast heart rate, rapid breathing, sweating: this might be symptoms of a deficiency of oxygen in your tissues (hypoxia);
- quick or difficult breathing, drowsiness, headache, inability to think and sleepiness, which may be the signs of a high concentration of carbon dioxide in your blood (hypercapnia);
- altered voice (hoarseness);
- swelling of the mouth, lips, tongue and gums, high saliva production;
- fatigue, feeling of weakness, feeling hot, pain at the site of injection;
- nerve injury.

**Reporting of side effects**
If you get any side effects, talk to your doctor or dentist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system 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 3% Plain

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage condition.
Do not freeze.

Do not use this medicine after the expiry date, which is stated on the cartridge label and carton after EXP.
The expiry date refers to the last day of that month.
Do not use this medicine if you notice that the solution is not clear and colourless.

The cartridges are for single use. The medicine administration should take place immediately after the opening of the cartridge. Unused solution must be discarded.

Do not throw away any medicines via wastewater or household. Ask your dentist, doctor or pharmacist how to throw away medicines you no longer use.
These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Scandonest 3% Plain contains**

- The active substance is mepivacaine hydrochloride 30 mg/ml;
  Each cartridge of 1.7 ml of solution for injection contains 51 mg of mepivacaine hydrochloride.
  Each cartridge of 2.2 ml of solution for injection contains 66 mg of mepivacaine hydrochloride.
- The other ingredients are: sodium chloride, sodium hydroxide and water for injection.

**What Scandonest 3% Plain looks like and contents of the pack**

This medicine is a clear and colourless solution. It is packed in a glass cartridge with a rubber seal kept in place by an aluminium cap.

The marketed presentation is cartridges of 1.7 ml or 2.2 ml contained in box of 50 cartridges.

**Marketing Authorisation Holder and Manufacturer**

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

**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| Austria: | Scandonest 3% ohne Vasokonstriktor – Zylinderampullen |
| Belgium: | Scandonest 3% sans Vasoconstricteur, solution injectable |
| Bulgaria: | Scandonest 30 mg/ml, solution for injection |
| Croatia: | Scandonest 30 mg/ml otopina za injekciju |
| Denmark: | Scandonest, 30 mg/ml, injektionsvæske, opløsning |
| Estonia: | Scandonest, 30 mg/ml süstelahus |
| Finland: | Scandonest 30 mg/ml, injektioneste, liuos |
| France: | Scandonest 30 mg/ml, solution injectable à usage dentaire |
| Germany: | Scandonest 3% ohne Vasokonstriktor, Injektionslösung |
| Greece: | Scandonest 3 %, ενέσιμο διάλυμα |
| Hungary: | Scandonest 30 mg/ml oldatos injekció |
| Ireland: | Scandonest 3% w/v, Solution for Injection |
| Italy: | SCANDONEST 3% senza vasocostrittore soluzione iniettabile |
| Latvia: | Scandonest 30 mg/ml šķīdums injekcijām |
| Lithuania: | Scandonest 30 mg/ml injekcinis tirpalas |
| Luxembourg: | Scandonest 3% sans Vasoconstricteur, solution injectable |
| Malta: | Scandonest 30 mg/ml, solution for injection |
| Netherlands: | Scandonest 3% zonder vasoconstrictor, oplossing voor injectie |
| Norway: | Scandonest Plain 30 mg/ml injeksjonsvæske, oppløsning |
| Poland: | Scandonest 30 mg/ml, roztwór do wstrzykiwań |
| Portugal: | Scandonest 30 mg/ml, solução injectável |
| Romania: | Scandonest 3% Plain, soluţie injectabilă |
| Slovakia: | Scandonest 3%, injekčný roztok |
| Slovenia: | Scandicaine 30 mg/ml raztopina za injiciranje |
| Spain: | Scandonest 30 mg/ml, solución inyectable |
| Sweden: | Scandonest 30 mg/ml, injektionsvätska, lösning |
| United Kingdom: | Scandonest 3% Plain, solution for injection |

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SEPTODONT
58 rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France
Tel.: 33 (0)1 49 76 70 00

## The following information is intended for healthcare professionals only:

### Posology and method of administration

The medicinal product should only be used by or under the supervision of dentists, stomatologists or other clinicians sufficiently trained and familiar with diagnosis and treatment of systemic toxicity. The availability of appropriate resuscitation equipment and medication and adequately trained staff is recommended before induction of regional anaesthesia with local anaesthetics to enable prompt treatment of any respiratory and cardiovascular emergencies. The patient's state of consciousness should be monitored after each local anaesthetic injection.

Posology

As the absence of pain is related to the patient individual sensibility, the lowest dose of anaesthetic leading to effective anaesthesia should be used. For more extensive procedures one or more cartridges may be required, without exceeding the maximum recommended dose.

For adults, the maximum recommended dose is of 4.4 mg/kg of body weight with an absolute maximum recommended dose of 300 mg for the individuals above 70 kg of body weight corresponding to 10 ml of solution.

Of note, the maximum quantity has to take into account the patient's body weight. As patients possess different body weights, each patient possess a different maximum allowed quantity of mepivacaine that can tolerate. Additionally, there are important individual variations with regards to the onset and duration of action.

The following table lists the maximum allowed doses in adults for the most commonly used anaesthetic techniques and the equivalent in number of cartridges:

| Weight (kg) | Mepivacaine hydrochloride dose (mg) | Volume (ml) | Equivalent* in cartridge numbers (1.7 ml) | Equivalent* in cartridge numbers (2.2 ml) |
|---|---|---|---|---|
| 50 | 220 | 7.3 | 4.0 | 3.0 |
| 60 | 264 | 8.8 | 5.0 | 4.0 |
| ≥70 | 300 | 10.0 | 5.5 | 4.5 |

* Rounded to the nearest half-cartridge

*Paediatric population*
Scandonest 3% Plain is contraindicated in children below 4 years of age (ca. 20 kg body weight).

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: ~ ¼ cartridge (15 mg of mepivacaine hydrochloride) for a 20 kg child.

Maximum recommended dosage:
The maximum recommended dose in paediatric population is 3 mg of mepivacaine/kg (0.1 ml mepivacaine/kg).

The following table lists the maximum allowed dose in children and the equivalent in number of cartridges:

| Weight (kg) | Mepivacaine hydrochloride dose (mg) | Volume (ml) | Equivalent* in cartridge numbers (1.7 ml) | Equivalent* in cartridge numbers (2.2 ml) |
|---|---|---|---|---|
| 20 | 60 | 2 | 1.2 | 0.9 |
| 35 | 105 | 3.5 | 2.0 | 1.5 |
| 45 | 135 | 4.5 | 2.5 | 2.0 |

* Rounded to the nearest half-cartridge

*Special populations*
Due to the lack of clinical data, particular precaution should be used in order to administer the lowest dose leading to efficient anaesthesia in:
- elderly people,
- patients with renal or hepatic impairment.

Mepivacaine is metabolized by the liver and can lead to elevated plasma levels in patients with hepatic impairment, in particular after repeated use. In case a reinjection is required, patient should be monitored, to identify any sign of relative overdose.

*Concomitant use of sedatives to reduce patient anxiety:*

If sedative medication is administered, the maximum safe dose of mepivacaine may be reduced due to an additive effect of the combination on central nervous system depression.

Method of Administration

Infiltration and perineural use
For single use

*Precautions to be taken before administering the medicinal product*
The medicinal product should not be used if cloudy and discoloured.
The rate of injection should not exceed 1 ml of solution per minute.
Local anaesthetics should be injected with caution when there is inflammation and/or infection at the site of the injection. The injection rate shall be very slow (1 ml/min).

*Risk associated with an accidental intravascular injection*
Accidental intravascular injection (e.g.: inadvertent intravenous injection into the systemic circulation, inadvertent intravenous or intra-arterial injection in the head area and neck area) may be associated with severe adverse reactions, such as convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest, due to the sudden high level of mepivacaine in the systemic circulation.
Thus, to ensure that the needle does not penetrate a blood vessel during injection, aspiration should be performed before the local anaesthetic product is injected. However, the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.
*Risk associated with intraneural injection*
Accidental intraneural injection may lead the drug to move in retrograde manner along the nerve.
In order to avoid intraneural injection and to prevent nerve injuries in connection with nerve blockades, the needle should always be slightly withdrawn if electric shock sensation is felt by the patient during injection or if the injection is particularly painful. If needle nerve injuries occur, the neurotoxic effect could be aggravated by mepivacaine's potential chemical neurotoxicity as it may impair the perineural blood supply and prevent mepivacaine local wash-out.

### Overdose

Types of overdose

Overdose of local anaesthetics may be absolute, resulting from the injection of excessive doses, or relative, resulting from the injection of a normally non-toxic dose under particular circumstances. These include inadvertent intravascular injection or abnormal rapid absorption into the systemic circulation, or delayed metabolism and elimination of the product.

Symptoms

In case of relative overdose, patients generally present symptoms within 1-3 minutes. Whereas in case of absolute overdose, signs of toxicity, depending on the injection site, appear about 20-30 minutes after the injection.
Toxic effects are dose-dependent, comprising progressively more severe neurological manifestations, followed by vascular, respiratory and finally cardiovascular signs such as hypotension, bradycardia, arrhythmia and cardiac arrest.

CNS toxicity occurs gradually, with symptoms and reactions of progressively increasing severity. Initial symptoms include agitation, a feeling of intoxication, a sensation of numbness in the lips and tongue, paraesthesia around the mouth, dizziness, visual and hearing disturbances, and buzzing in the ears. Manifestation of these effects during injection of the product is a warning signal and the injection should be stopped immediately.

Cardiovascular symptoms occur at plasma levels exceeding those inducing CNS toxicity and are therefore generally preceded by signs of CNS toxicity, unless the patient is under general anaesthesia or is heavily sedated (e.g. by a benzodiazepine or barbiturate). Loss of consciousness and the onset of generalized seizures may be preceded by premonitory symptoms such as joint and muscle stiffness, or twitching. Seizures may last from a few seconds to several minutes and rapidly lead to hypoxia and hypercapnia, as a result of increased muscular activity and insufficient ventilation. In severe cases, respiratory arrest may occur.

Undesirable toxic effects may appear at plasma concentrations upper than 5 mg/l, and convulsions could appear with 10 mg/l or higher. Limited data of overdose are available.

Acidosis exacerbates the toxic effects of local anaesthetics.

If a rapid intravascular injection is administered, a high blood concentration of mepivacaine in the coronary arteries may lead to myocardial failure, possibly followed by cardiac arrest, before the CNS is affected. The data on this effect remains controversial (see Sections 4.4 and 5.1).

Management

If signs of acute systemic toxicity appear, injection of the local anaesthetic should be stopped immediately.
CNS symptoms (convulsions, CNS depression) must promptly be treated with appropriate airway/respiratory support and the administration of anticonvulsant drugs.
Optimal oxygenation and ventilation and circulatory support as well as treatment of acidosis are of vital importance.
If cardiovascular depression occurs (hypotension, bradycardia), appropriate treatment with intravenous fluids, vasopressor, and/or inotropic agents should be considered. Children should be given doses commensurate with age and weight.
Should cardiac arrest occur, a successful outcome may require prolonged resuscitative efforts.

Dialysis is not effective in treating an overdose of Mepivacaine. Elimination can be accelerated by acidifying the urine.

**Special precautions for disposal and other handling**

The cartridges are intended for single use. The drug administration to the patient should take place immediately after the opening of the cartridge.

As for any cartridge, the diaphragm should be disinfected prior to use. It should be carefully swabbed either with 70% ethyl alcohol or with 90% pure isopropyl alcohol for pharmaceutical use.

The cartridges should under no circumstance be dipped into any solution whatsoever.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

SEPTODONT
58 rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France
Tel.: 33 (0)1 49 76 70 00