Package leaflet: Information for the patient

Scandonest 3% w/v, 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 is and what it is used for

Scandonest 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

Do not use Scandonest:
- 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 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);

- a 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
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 (antiarrythmics);
- Cytochrom P450 1A2 inhibitors;
- medicines used to treat hypertension (propranolol).

Scandonest 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 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

Scandonest 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 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.

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 (paresthesia);
- 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 color 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, preferably through the online reporting option accessible from the HPRA homepage. A downloadable report form is also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie ,e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Scandonest

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 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 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

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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

SEPTODONT Ltd
Units R & S
Orchard Business Centre
St Barnabas Close
Allington, Maidstone
Kent ME 16 0JZ – UK
ENGLAND
Tel: +44 (0) 1622 695520

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Scandonest 3% ohne Vasokonstriktor, Injektionslösung
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

This leaflet was last revised in.

Detailed information on this medicine is available on the Health Products Regulatory Authority website: http://www.hpra.ie.