PACKAGE LEAFLET: INFORMATION FOR THE USER

Lignospan Special (20 mg + 12.5 microgram/ml) solution for injection

Lidocaine hydrochloride and Adrenaline (Epinephrine)

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, pharmacist or dentist.
- 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, pharmacist or dentist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT LIGNOSPAN SPECIAL IS AND WHAT IT IS USED FOR

Lignospan Special is given by injection to cause loss of feeling before and during dental procedures.
Lignospan Special contains two active ingredients: lidocaine hydrochloride, a local anaesthetic which allows to prevent the pain, and adrenaline tartrate, a vasoconstrictor which makes it last longer (adrenaline narrows the blood vessels at the site of injection, which keeps the anaesthetic where needed for a longer time).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LIGNOSPAN SPECIAL

Do not use Lignospan Special:
- if you are allergic to lidocaine hydrochloride or adrenaline tartrate or to any of the other ingredients of this medicine (listed in section 6);
- if you are allergic to other local anaesthetics called amide type anaesthetics.

Due to the presence of lidocaine, do not use this medicine:
- if you suffer from severe heart rhythm disorders (e.g. second and third AV block);
- if you suffer from a condition called *Prophyria* which causes either neurological complications or skins problems;
- if you are epileptic and not adequately controlled by treatment.

Due to the presence of adrenaline tartrate (adrenaline), a vasoconstrictor, do not use this medicine:
- if you have very high blood pressure (hypertension);
- if you have severe heart failure (ischemic heart disease);
- if you have fast irregular heartbeat (tachyarrhythmia);
- if your thyroid is severely overfunctionning (thyrotoxicosis);
- if you have a tumour called *pheochromocytoma*.

Warnings and precautions:

Talk to your dentist before using Lignospan Special:
- if you have problems with your blood vessels (e.g. narrowing and hardening of the arteries that supply the legs and feet);
- if you have irregular heartbeat (arrhythmia);
- if you have heart failure;
- if you have low pressure (hypotension);
- if you are epileptic;
- if you have problems with your liver;
- if you have problems with your kidney;
- if you suffer from a disease called *Myasthenia Gravis* causing weakness in the muscles;
- if you receive a treatment with antiplatelets / anticoagulants;
- if you suffer from uncontrolled diabetes;
- if you suffer from a disease called acute angle-closure glaucoma which affects your eyes;
- if you are under the influence of illicit drug;
- if you are more than 70 years old;
- if you have inflammation or infection in the area to be injected;
- if you are allergic to sulphites.

Children
Lignospan Special is indicated in children. Special care has to be exercised when treating children below 4 years.

Other medicines and Lignospan Special:
Tell your dentist, doctor, pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking the following medicines, as precautions should be taken by your dentist:
- other local anaesthetics;
- opioid sedatives, used to relieve pain;
- inhibitors of metabolism, (used to treat heartburn and peptic ulcers);
- heart and blood pressure medicines (for example guanadrel, guanethidine and beta blockers like propranolol and nadolol);
- some anaesthetics that are inhaled (such as halotane);
- tricyclic antidepressants used to treat depression (such as amitriptyline, desipramine, imipramine, nortriptyline, maprotiline and protriptyline);
- MAO inhibitors used to treat depressive or anxiety disorders (such as brofaromine, moclobemide, toloxatone, phenelzine, tranylcypromine);
- COMT inhibitors used to treat Parkinson's disease (such as entacapone or tolcapone);
- drugs with combination of adrenergic-serotoninergic effect, used to treat depression, obsessive-compulsive disorders and anxiety (such as venlafaxine, milnacipran, sertraline);
- medicines used to treat irregular heartbeats (for example digitalis, quinidine);
- medicines used for migraine attacks (such as methysergide or ergotamine);
- sympathomimetic vasopressors such as oxymetazoline used to treat swelling or inflammation of the nose;
- other sympathomimetics;
- neuroleptic drugs (for example phenothiazines);

If sympathomimetic vasopressor such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline have been used within the past 24 hours, the planned dental treatment should be postponed.

Lignospan Special with food and drink

You should avoid chewing-gum or eating until normal sensation is restored after using this medicine. Otherwise there is a risk that you will bite your lips, cheeks or tongue.

Pregnancy and 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.
This product can be used during pregnancy and breast-feeding without any risk to the foetus or to the breastfed child provided that it is taken as prescribed.
No effects on fertility were observed in preclinical studies.

Driving and using machines
Lidocaine in combination with adrenaline may have minor influence on the ability to drive and use machines. Dizziness (including vertigo, vision disorder and fatigue) may occur following administration of this product (see section 4. Side effects). You should not leave the dental office within 30 minutes following the dental procedure.

Lignospan Special contains sodium and potassium metabisulfite (E224).
- 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 respiratory disorders. This medicine contains potassium less than 1 mmol (39 mg) per cartridge, i.e. essentially "potassium-free".

3. HOW TO USE LIGNOSPAN SPECIAL

Dentists and stomatologists are trained to use Lignospan Special, by a slow local injection. One cartridge is usually sufficient for routine operations.
Your dentist will chose the composition and adjust the dosage according to your age, your health and the dental procedure. The lowest dose leading to efficient anaesthesia should be used.
This medicine is given as an injection in the oral cavity.

The local anaesthetic effect depends on the technique used and on the dental act. If you have any further questions, please ask your dentist.

Use in children
Special care has to be exercised when treating children below 4 years. The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation.
If the physician or dentist uses more Lignospan Special than he/she should
If signs of acute systemic toxicity appear, administration should immediately be stopped and emergency medical assistance should be summoned.
If you have any further question on the use of this medicine, ask your dentist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

<u>Immediately</u> inform your dentist, doctor or pharmacist if you experience one of the following serious side effects:

- Rash, itching, swelling of the face, lips, gums, tongue and/or throat and difficulty breathing: this might be symptoms of an allergic / anaphylactic reaction;
- Loss of consciousness;
- Convulsion;
- Horner's syndrome - a combination of drooping of the eyelid and constriction of the pupil;
- Double vision, drooping or falling of the upper eyelid, enlarged pupil: this may be the first signs of a third nerve palsy;
- Vision loss;
- Failure of the heart to contract effectively (myocardial depression, cardiac arrest), rapid and erratic heartbeats (ventricular fibrillation), severe and crushing chest pain (angina pectoris);
- Abnormally slow breathing (respiratory depression), stopping breathing (apnoea);
- 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);
- Painful and/or darkening tooth possibly with gum boil, which are the signs that the pulp tissue inside your tooth is dying.

Other side effects not listed above may also occur:

Common side effects (may affect up to 1 in 10 people):
- Pain due to nerve damage (neuropathic pain);
- Numbness or reduced sens of touch in and around the mouth,
- Metallic taste, taste disturbance or loss of taste function,
- Headache;
- Dizziness (lightheadedness);
- Tremor;
- Palpitations;
- Abnormal rapid heartbeat (tachycardia);
- Low blood pressure (hypotension), high blood pressure (hypertension);
- Pallor;
- Shortness of breath (dyspnoea);
- Procedural pain, contusion.

Uncommon side effects (may affect up to 1 in 100 people):
- Nausea, vomiting;
- Rash, itching (pruritus);
- Muscle pain (myalgia), joint pain (arthralgia).

Rare side effects (may affect up to 1 in 1,000 people):
- Difficulty in breathing, wheezing (bronchospasm, asthma);
- Hives (urticarial);
- Coma;
- Presyncope, syncope;
- Confusional state, disorientation;
- Dizziness;
- Speech impairment, excessive talkativeness;
- Balance disorder (disequilibrium);
- Drowsiness;
- Involuntary eye movement (nystagmus);
- Drooping or falling of the lower eyelid, constriction of the pupil;
- The posterior displacement of the eyeball within the orbit due to changes in the volume of the orbit - called *Enophthalmos*;
- Vision blurred, problems clearly focusing an object, visual impairment.

Very rare side effects (may affect up to 1 in 10,000 people):
- Oral abscess;
- Inflammation of the alveolar bone (alveolar osteitis);
- Euphoric mood;
- Anxiety, nervousness, agitation, restlessness;
- Burning sensation, prickling, skin sensation, tingling, with no apparent physical cause (paresthesia);
- Ringing in the ears (tinnitus), over-sensitivity of hearing;
- Heartbeat coordination problems (conduction disorders, atrioventricular block), abnormal slow heartbeat;
- Widening or narrowing of blood vessels;
- Hot flush;
- Excessive sweating (hyperhidrosis);
- Muscle twitch, muscle stiffness, lockjaw (trismus);
- Injection site pain;
- Fatigue, weakness;
- Feeling hot or feeling cold.

Not Known (frequency cannot be estimated from the available data):
- Abnormally slow or rapid breathing;
- A high concentration of carbon dioxide in the blood (hypercapnia) which may damage your brain, liver and other organs;
- Yawning;
- Respiratory disorders, hoarseness;
- Sloughing and ulceration of the gums;
- Difficulty in swallowing;
- Inflammation of the mouth and lips (stomatitis), tongue (glossitis), or gum (gingivitis);
- Diarrhea;
- Chills (shivering);
- Swelling at the injection site;
- Malaise, discomfort;
- Abnormal elevation of body temperature (pyrexia).

Additional side effects in children and adolescents

The safety profile was similar in children and adolescents from 4 to 18 years old compared to adults.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 (see details below).
By reporting side effects you can help provide more information on the safety of this medicine.
IRELAND: FREEPOST, HPRA Pharmacovigilance
Earlsfort Terrace, Dublin 2, Ireland
Tel: +353 1 6764971, Fax: +353 1 6762517
Website:www.hpra.ie, e-mail: medsafety@hpra.ie

5. HOW TO STORE LIGNOSPAN SPECIAL

Keep this medicine out of the sight and reach of children.
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.
Store below 25°C.
Keep the cartridge in the outer carton tightly closed, in order to protect from light.
Do not freeze.
Do not use this medicine if you notice that the solution is not clear and colourless.
The cartridges are for single use. If only a portion of a cartridge is used, the remainder must be discarded.
Do not throw away medicines via wastewater or household waste.
Ask your 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 Lignospan Special contains

- The active substances are lidocaine hydrochloride, anhydrous (as lidocaine hydrochloride) 20 mg/ml and adrenaline (epinephrine) (as tartrate) 12.5 micrograms/ml.
- The other ingredients are sodium chloride, potassium metabisulfite (E224), disodium edetate, sodium hydroxide, water for injection.

What Lignospan Special looks like and contents of the pack

Lignospan Special is a solution for injection.
It is a clear and colourless solution.
It is packed in dental clear type I glass cartridges sealed with a rubber stopper and aluminium ring at one end and a rubber plunger at the other.
Each box contains 50 cartridges of 1.8 ml or 2.2 ml.

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.

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

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The following information is intended for healthcare professionals only:

Posology and method of administration

Posology

As the absence of pain is related to patient individual sensibility, the lowest dose of anaesthetic leading to effective anaesthesia should be used.

Adults

For a routine procedure, the normal dose is 1 cartridge, but the contents of less of a cartridge may be sufficient for effective anaesthesia. At the discretion of the dentist, more cartridges may be required for more extensive procedures without exceeding the maximum recommended dose.
The maximum recommended dose is 7 mg/kg of body weight, with an absolute maximum recommended dose of 320 mg of lidocaine and 0.2 mg of adrenaline for individuals above 50 kg of body weight, corresponding to 16 ml of lidocaine with adrenaline solution, i.e. 9 cartridges of 1.8 ml and 7 cartridges of 2.2 ml.

Paediatric population

Special care has to be exercised when treating children below 4 years. The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. The anaesthesia technique should be selected carefully. Painful anaesthesia techniques should be avoided. The behaviour of the child during treatment has to be monitored carefully. The average dose to be used is in the range of 20 mg to 30 mg lidocaine hydrochloride per session.
The dose in mg of lidocaine hydrochloride which can be administered in children may alternatively be calculated from the expression: child's weight (in kilograms) x 1.33.
Do not exceed the equivalent of 5 mg of lidocaine hydrochloride per kilogram of body weight.

		Equivalent in cartridges numbers	
Weight (kg)	Lidocaine dose (mg)	1.8 ml	2.2 ml
20	100	3	2
30	150	4	3
40	200	6	5
50	250	7	6

• Special populations

Due to the lack of clinical data, particular precaution should be used in order to administer the lowest dose leading to effective anaesthesia in elderly patients over 70 years old and in patients with renal or hepatic impairment.

Method of administration:

Infiltration and perineural use in oral cavity.
Before injection, aspiration is always recommended to avoid intravascular injection.
Major systemic reactions as a result of accidental intravascular injection can be avoided in most cases by an injection technique after aspiration with a slow injection: the rate of injection should not exceed 1 ml of solution per minute.
To avoid risk of infection (e.g. hepatitis transmission), syringe and needles used to draw up the solution must always be fresh and sterile.
For single use. Any unused solution should be discarded.
The medicinal product should not be used if cloudy or discoloured.
For information relevant to the handling of the product, see section 6.6 of the SmPC.

Special warning and precautions

- Risk associated with an accidental intravascular injection:

Accidental intravascular injection (e.g.: inadvertent intravenous injection into systemic circulation, inadvertent intravenous or intraarterial 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 adrenaline and/or lidocaine 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 lidocaine's potential chemical neurotoxicity and the presence of adrenaline as it may impair the perineural blood supply and prevent lidocaine local wash-out.

- Risk of Takotsubo cardiomyopathy or stress-induced cardiomyopathy:

Stress cardiomyopathy induced by injected catecholamines has been reported.
Because of the presence of adrenaline, precautions and monitoring should be enhanced in the following situations: patients stressed prior dental procedure.
Any previous knowledge of such underlying conditions in patients requiring dental anaesthesia should be minded and a minimal dose of local anaesthetic with vasoconstrictor used.
Concomitant use of other medicinal products may require thorough monitoring (see section 2-Other medicines of this leaflet or section 4.5-Interactions of the SmPC).

Overdose

• **Types of overdose**
Local anaesthetic overdose in the largest sense is often used to describe:
• absolute overdose,
• relative overdose:
  - inadvertent injection into a blood vessel, or
  - abnormal rapid absorption into the systemic circulation, or
  - delayed metabolism and elimination of the product.

• **Symptomatology**

• *Due to lidocaine:*

The symptoms are dose-dependent and have progressive severity in the realm of neurological manifestations, followed by vascular toxicity, respiratory toxicity and finally cardiac toxicity (detailed in section 4.8 of the SmPC).

• *Due to adrenaline:*

Overdose of adrenaline may cause cardiovascular effects.

• **Treatment of overdose**

The availability of resuscitation equipment should be ensured before the onset of dental anaesthesia with local anaesthetics.
If signs of acute toxicity are suspected, the injection of this product must immediately be stopped.
Oxygen should rapidly be administered, if necessary by assisted ventilation. Change patient position to supine position if necessary.
In case of cardiac arrest, immediate initiation of cardiopulmonary resuscitation is necessary.

Special precautions for disposal

As for any cartridge, the diaphragm should be disinfected just 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 circumstances be dipped into any solution whatsoever.

One cartridge can only be used for one single patient during one single session.
No opened cartridge of anaesthetic solution should be reused. If only a part is used, the remainder must be discarded.

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

For professional use by dentists and stomatologists

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