

Lignospan Special
Utilycaine – Lignokent – Eurocaine 2% - Rexocaine

Solution for injection
Lidocaine hydrochloride and adrenaline

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

In this leaflet:

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

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. It contains two active ingredients:

- lidocaine hydrochloride, a local anaesthetic, which prevents pain,
- adrenaline tartrate, 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.

LIGNOSPAN SPECIAL is for adults, children and adolescents.

Only a dentist can administer this product.

2. Before you use LIGNOSPAN SPECIAL

Do not use LIGNOSPAN SPECIAL

- if you are allergic (hypersensitive) to one of the active ingredients (lidocaine hydrochloride or adrenaline tartrate) or to any of the other ingredients (refer to section 6)
- if you are allergic to local anaesthetics called amide type anaesthetics,
- if you are asthmatic or have suffered difficulty with your breathing as a result of taking medicines which contain ingredients called sulphites or metabisulphites,
- 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,

Take special care with LIGNOSPAN SPECIAL

Before receiving this medicine, tell your dentist if:

- you have problems with your heart or blood vessels,
- you have problems with your liver,
- you have a severe infection or an inflammation in the area where the injection will be done.
- the child being treated is under 4 years old

Using other medicines

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

- Do not use LIGNOSPAN SPECIAL if you are taking or have taken medicines for depression in the last two weeks.

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

- medicines used to reduce your blood pressure (e.g. betablockers like propranolol or vasopressor drugs like dihydroergotamine),
- medicines used to reduce patient apprehension (e.g. sedatives). In this case, the dosage of anaesthetic should be reduced.

Pregnancy and breast-feeding

Ask your doctor or pharmacist 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 LIGNOSPAN SPECIAL

LIGNOSPAN SPECIAL contains

- less than less than 1 mmol (23mg) sodium per cartridge, i.e. essentially "sodium free".
- potassium metabisulphite: it may rarely cause severe allergic reactions and difficulty in breathing (bronchospasm).

3.How to use LIGNOSPAN SPECIAL

Your dentist will explain to you why you are being treated with LIGNOSPAN 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. LIGNOSPAN SPECIAL is injected between two teeth.

If your dentist uses more LIGNOSPAN 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, LIGNOSPAN SPECIAL 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 LIGNOSPAN SPECIAL.

Administration of LIGNOSPAN SPECIAL may cause high plasma levels in active substances (lidocaine and/or adrenaline), especially overdose or unintended injection. Symptoms include: effects on your senses (hearing, sight, behaviour), effects on your heart and blood vessels, effects on your immune defences (diminished tolerance).

As complications to the manifestations of progressive cerebral hypoxia (decrease below normal levels of oxygen in tissue) and seizure or cardiovascular problem, sweating, feeling of faintness, changes in pulse or sensorium, vasovagal reaction might occur.

Allergic (hypersensitivity) reactions may occur when using this medicine. Symptoms of these reactions might include: rash, itching, swelling of the throat and difficulty breathing. Inform your dentist, doctor or pharmacist immediately if one of these effects applies to you.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- failure of cardiac circulation (cardiovascular collapse) which may lead to cardiac arrest, loss or abnormality of rhythm (arrhythmia), conduction disorders, drop in blood pressure (hypotension), convulsions, feeling of well-being commonly exaggerated (euphoria), unconsciousness, malaise, confusion, dizziness, headache, If you are in an upright position, a vasovagal reaction (relating to the action of the nerve upon the blood vessels) may develop, slow or rapid heartbeats (bradycardia or tachycardia), irregular pulsation of heart (palpitations), lightheadedness, feeling nervous (nervousness), apprehension, agitation, drowsiness, buzzing in the ears (tinnitus), blurred or double vision, nausea, vomiting, sensations of heat, cold or numbness, uncontrolled eye movement (twitching), trembling.

The following very rare side effects affect 1 of 10,000 patients treated:

- severe allergic reactions (anaphylactoid reactions) characterized by swelling of the face, lips and/or tongue, difficulty breathing.
- allergic reactions characterized by skin rash (cutaneous lesions), eruption of itching wheals (urticaria), swelling (edema)

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

5. How to store LIGNOSPAN SPECIAL

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). It should not be frozen.

6. Further information

What LIGNOSPAN SPECIAL contains

- Active substances: each ml of solution for injection contains:
 - 20 mg of lidocaine hydrochloride,
 - 12.5 micrograms of adrenaline (epinephrine).
- The other ingredients are: potassium metabisulphite (E224), sodium chloride, sodium edetate, sodium hydroxide solution and water for injection.

What LIGNOSPAN SPECIAL looks like and content of the pack

It is a solution for injection.

LIGNOSPAN SPECIAL is available in boxes containing 50 cartridges of 1.8 ml or of 2.2 ml.

Marketing authorisation holder

Septodont Ltd, Units R & S
Orchard Business Centre
St Barnabas Close
Allington, Maidstone
Kent ME16 0JZ - UK

Manufacturer

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

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If more PILs are necessary, call free number 0800435155.