

Variation to the Registration of Lignospan Special

Consumer Medicine Information

WHAT'S IN YOUR MEDICINE

Active ingredients:

- Lignocaine hydrochloride 44 mg (2.2 mL Cartridge), 36 mg (1.8 mL Cartridge)
- Adrenaline (as acid tartrate) 27.5 µg (2.2 mL Cartridge), 22.5 µg (1.8 mL Cartridge)

Other ingredients:

- Sodium chloride,
- sodium hydroxide,
- disodium edetate,
- potassium metabisulfite,
- water for injections.

Presentation:

Box of 50 cartridges single use, containing each 2.2 mL or 1.8 mL of solution.

WHAT YOUR MEDICINE IS USED FOR AND HOW IT WORKS

LIGNOSPAN SPECIAL is given by injection to cause loss of feeling before and during dental procedures. It contains two active ingredients: Lignocaine hydrochloride, a local anaesthetic 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 it's needed for a longer time) and controls bleeding during the surgery.

ADVICE BEFORE USING THE MEDICINAL PRODUCT:

In deciding to use a medicine, the risks of using the medicine must be weighed against the good it will do. This is a decision you and your dentist will make. For local anaesthetics, the following should be considered.

This product should not be used if:

- You are allergic to:
 - adrenaline
 - lignocaine, procaine or any local anaesthetic
 - sodium metabisulfite or any sulfites
 - any other ingredient included in the product.Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- You have arterial hypertension (high blood pressure), coronary disease or valvular cardiac disease (heart or circulation problems).
- You have an over active thyroid gland, whether or not treated for this.
- You have cerebral arteriosclerosis (hardening in the brain arteries).
- You have an inflammation (pain, swelling, redness and heat) or sepsis (blood infection) in the region of the proposed injection.

This product should be used with caution if:

- You have problems with your heart, blood vessels, circulation and heart rhythm.
- You have epilepsy.
- You have high blood pressure, asthma, diabetes and thyroid problems.

- You have hepatic (liver) or renal (kidney) diseases.
- You have an allergy to Para Amino Benzoic Acid (PABA) derivatives (such as procaine and benzocaine).
- You have prostatic hypertrophy (enlarged prostate).
- You are pregnant or breast-feeding.

LIGNOSPAN SPECIAL MAY INTERACT WITH OTHER MEDICINES.

It should not be used if you are taking:

- Mono Amine Oxidase Inhibitors (MAOI) or tricyclic antidepressants (medicines used to treat depression).
- Phenothiazines or butyrophenones (medicines used to treat mental illnesses).
- Vasopressor drugs (medicines used to elevate blood pressure).
- Ergot type oxytocic drugs (medicines used to induce labour in pregnant women).

It should be used with caution if you are taking:

- Beta-blockers (medicines used to lower high blood pressure and/or treat heart problems).
- Guanethidine, a medicine used for pain or in surgery.
- Hypoglycaemic drugs (medicine used to treat high blood sugar).
- Anti-arrhythmic drugs and amiodarone (medicines used to treat irregular heartbeats).
- Anti-epileptic drugs (medicines used to treat epilepsy).
- Cardiac glycosides (medicines used to treat heart failure).
- Cimetidine (medicine used to treat reflux and stomach or duodenal ulcers).
- Halogenated compounds (medicines used in anaesthetics such as chloroform, halothane, or cyclopropane).

These medicines may be affected by LIGNOSPAN SPECIAL, or may affect how well it works. Please make sure that you tell your dentist about all medicines which you are taking, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Your dentist will advise you what to do if you are taking any of these medicines.

HOW THIS MEDICINE WILL BE USED:

Your dentist will explain to you why you are being treated with LIGNOSPAN SPECIAL and what dose you will be administered. Your dentist will inject LIGNOSPAN SPECIAL into your oral (mouth) cavity. This will result in an area of numbness at the site of injection. One cartridge is usually sufficient but your dentist may give you a greater quantity. He will adjust the dosage according to your age, your health and the dental work to be performed.

IN CASE OF OVERDOSE:

Your dentist will determine the amount of solution, which is needed to provide pain control during your treatment, and it is very unlikely that you would receive too much LIGNOSPAN SPECIAL. However, some persons tolerate lignocaine and adrenaline less well than others and the signs and symptoms of too much of these substances in your blood include: nervousness, dizziness, blurred vision, nausea, trembling, convulsions, slow or irregular heart beat, troubled breathing.

Tell your dentist immediately if you experience any of these symptoms during or shortly after your treatment.

Whenever you are given LIGNOSPAN SPECIAL, equipment will be available to care for you if an overdose happens.

While you are being given LIGNOSPAN SPECIAL

Things you must not do:

- Do not eat or drink anything hot until the feeling has returned to your mouth. You may burn or bite yourself.

Things to be careful of:

- Be careful driving or operating machinery until you know how LIGNOSPAN SPECIAL 1/80.000 affects you. You may be drowsy and your reflexes may be slow.
- Do not drink alcohol immediately before or after you are given LIGNOSPAN SPECIAL.
- If you drink alcohol while you are being given LIGNOSPAN SPECIAL, your blood pressure may drop making you feel dizzy and faint.
- Please talk to your dentist or pharmacist about these possibilities if you think they may bother you.

UNWANTED EFFECTS

LIGNOSPAN SPECIAL like most other medicines may cause side effects in some patients.

Although not all of these side effects may occur, if they do occur they may need medical attention. While you are in your dentist office, your dentist will carefully follow the effects of LIGNOSPAN SPECIAL. However, some effects may not be noticed or appear later.

Check with your dentist if any of the following side effects occur:

Common reactions:

- Infection and pain in the injection site
- Tingling and numbness of the hand and feet or increased feeling or sensitivity of the skin
- You are feeling nervous, nauseous or dizzy
- You have a headache
- You are trembling, have buzzing in the ears, blurred vision or have any abnormal feeling
- Your breathing is difficult
- Your heart is beating slowly or irregularly
- You have facial swelling or inflammation of gums
- You may have a loss of sensation and muscle function following the injection of LIGNOSPAN SPECIAL.

Resolution occurs generally within two weeks.

Very rare reactions:

There are some serious unwanted reactions, which may happen if LIGNOSPAN SPECIAL is given intravenously or you are very sensitive to it, it may cause:

- You have skin rash, hives or itching.
- Fits.
- Unconsciousness.
- Breathing problems.
- Low blood pressure.
- Slow heart beat.
- Collapse.

If you have them, you may have had a serious (allergic) reaction to LIGNOSPAN SPECIAL.

You may need urgent medical attention or hospitalisation.

Tell your dentist if you notice anything else that is making you feel unwell.

Some people may get other side effects while using LIGNOSPAN SPECIAL.

You may be allergic to sulfites and therefore show allergic symptoms to LIGNOSPAN SPECIAL as difficulty breathing or shortness of breath or skin reactions.

If you have problems with your blood vessels or have high blood pressure, you may react exaggeratedly to the adrenaline contained in LIGNOSPAN SPECIAL and develop a small injury at the site of injection.

STORAGE CONDITIONS

It is most unlikely that you will be asked to look after this medicine. Your dentist will keep it below 25°C and protected from light. He will not use this medicine after the expiry date printed on the package.

All medicines must be kept in a safe place out of the reach of children.

FURTHER INFORMATION

Remember this medicine is only for you. Only a dentist can administer this product. This leaflet provides only a summary of the information known about LIGNOSPAN SPECIAL. If you have any questions, want to know more about this medicine, or have some doubts, ask your dentist.

SPONSOR

Specialites Septodont,
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EMU PLAINS,
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DISTRIBUTOR

Henry Schein Regional Pty Ltd,
3 -11 Primrose Avenue,
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NSW 2018 Australia.

DATE OF INFORMATION

June 2003

1.8 mL - AUST R 49327

2.2 mL - AUST R 49328

LIGNOSPAN SPECIAL

(LIGNOCAINE HYDROCHLORIDE 2%,
ADRENALINE 1/80.000 INJECTION)
LOCAL AND REGIONAL ANAESTHETIC