

Lignospan special
(20 mg/ 12.5 microgram per ml)
solution for injection 1.8 ml and 2.2 ml

**Lidocaine Hydrochloride
Adrenaline (epinephrine)**

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 further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Lidocaine hydrochloride, Adrenaline (Epinephrine)

- 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 metabisulphite (E224), disodium edetate, sodium hydroxide solution, water for injection.

Marketing Authorisation Holder and Manufacturer:
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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).

Lignospan Special is packaged in clear type I glass cartridges sealed with a rubber stopper and aluminium ring at one end and a rubber plunger at the other.

The solution is clear, colourless and sterile.

The marketed presentations are boxes containing 50 x 1.8 or 2.2 ml glass cartridges.

2. BEFORE YOU USE LIGNOSPAN SPECIAL

Do not use Lignospan Special:

- if you are hypersensitive (allergic) to lidocaine or any other ingredients of Lignospan Special like the sulphites
- if you are suffering cardio-vascular affections like arterial hypertension, coronary disease or valvular cardiac disease.
- if you are suffering epilepsy, blood disease.

Take special care with Lignospan Special:

- if you are suffering hepatic affections, heart rhythm disorders
- if you are debilitated, elderly patient, acutely ill patient or child
- when the needle penetrates a blood vessel during injection, toxic reactions can appear due to overdose. To minimise the likelihood of intravascular injection, aspiration should be performed before and during the injection.

Using Lignospan Special with food and drink:

Avoid chewing-gum or any type of food as long as the anaesthesia persists. It is recommended not to take any food before you have recovered sensibility because of the risk of bites in your mouth (lips, jaws, tongue).

Pregnancy

The administration to pregnant women should be carried out with caution.

Ask your doctor or pharmacist for advice before using any medicine.

Breast-feeding

No information is available regarding excretion into human milk. That's the reason why the administration to nursing mothers should be carried out with caution.

Ask your doctor or pharmacist for advice before using this medicine.

Important information about some of the ingredients of Lignospan Special:

The medicinal product contains potassium metabisulphite (E224) which may rarely cause severe hypersensitivity reactions and give respiratory disorders.

This medicinal product contains less than 1 mmol sodium (23mg) and less than 1 mmol potassium (39mg) per cartridge i.e essentially "sodium-free" and "potassium-free".

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

- Antidepressant treatments may produce severe prolonged hypotension or hypertension.
- Vasopressor drugs and ergot-type oxytocic drugs may cause severe persistent hypertension or cerebrovascular accidents.
- The use of sedatives may have an addictive effect.
- Beta-adrenergic blocking agents may result in hypertension and bradycardia.

3. HOW TO USE LIGNOSPAN SPECIAL

The physicians or dentists are only authorised to inject Lignospan Special because they are trained in local anaesthesia techniques and their complications.

On average, one cartridge is usually sufficient for routine operations.

However, your doctor or dentist may decide to administer a smaller or greater amount of anaesthetic. He will adjust the dose according to your age, weight, health condition and to the type of surgery to be performed.

If you have the impression that the effect of Lignospan Special is too strong or too weak, talk to your doctor or pharmacist.

If the physician or dentist uses more Lignospan Special than he should, symptoms of overdose can appear:

- nervous manifestations like light-headedness, nervousness, apprehension, confusion, feeling of well-being commonly exaggerated, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat or cold, numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest
- cardiovascular manifestations like bradycardia, hypotension, cardiovascular collapse
- allergic reactions like cutaneous lesions, urticaria, oedema

Instructions:

- hyperventilation
- IV injection of an ultra-short acting barbiturate or a benzodiazepine
- oxygenation
- assisted ventilation

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lignospan Special can have side effects, although not everybody gets them

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 may appear later. Check with your dentist, doctor or pharmacist if any of the following side effects occur :

Very common:

- General effects : injection site pain, headache, face oedema, infection, gingivitis, loss of sensation and muscle function, chest pain, vomiting, neuralgia, arthralgia (pain in a point), myalgia (muscular pain).
- Effects on your skin: skin rash, sweating.



- Rare:

- Allergic reaction including swelling of the face, lips and/or tongue difficulty in breathing.

- Not known frequency:

- Effects on your senses: light headedness, blurred or double vision, sensation of heat, cold or nausea.
- Effects on your heart and blood vessels: slow or irregular hearbeats, low blood pressure;
- Effects on your lung: difficulty in breathing and abnormalities of breathing.

You may develop more severe reaction such as convulsion and reduced level of consciousness with possible arrest of breathing or heart. Emergency medical help should immediately be called.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING LIGNOSPAN SPECIAL

Keep out of the reach and sight of children.

Do not use Lignospan Special after the expiry date which is stated on the label and carton 'After EXP'. The expiry date refers to the last day of the month.

Do not freeze.

Do not store above 25°C.

Store in the original container in order to protect from light.

The cartridges are for single use. If only a portion of a cartridge is used, the remainder must be discarded.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

For any information about this medicinal product, please contact the local representative of the marketing authorisation holder.

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