Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lignospan Special (20 mg/12.5 microgram per ml) Solution for Injection 1.8 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine hydrochloride, anhydrous 20 mg/ml (as lidocaine hydrochloride). Adrenaline (epinephrine) 12.5 micrograms/ml (as adrenaline tartrate (epinephrine bitartrate)).

Each cartridge containing 1.8 ml of solution contains 36 mg of Lidocaine hydrochloride anhydrous (as lidocaine hydrochloride) and 22.5 micrograms of adrenaline (epinephrine) (as adrenaline tartrate (epinephrine bitartrate)).

Excipient(s) with known effect: Each ml also contains 1.20 mg of potassium metabisulfite (E224) and 0.11 mmol of sodium (2.602mg/ml).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless, sterile injection solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Local anaesthesia for dental procedures by infiltration or nerve block injections.

LIGNOSPAN SPECIAL is indicated in adults, children and adolescents.

4.2 Posology and method of administration

For professional use by dentists and stomatologists.

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 solution, i.e. 9 cartridges of 1.8 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.

		Maximum number of cartridges
Patient's body weight (kg)	Maximum recommended lidocaine dose (mg)	1.8 ml
20	100	3
30	150	4
40	200	6
50	250	7

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.

LIGNOSPAN SPECIAL must not be mixed with any other preparation for injection.

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.

4.3 Contraindications

- Hypersensitivity to lidocaine (or to any local anaesthetic agent of the amide type) or to adrenaline or to any of the excipients listed in section 6.1

- *Due to lidocaine*

- Severe conduction disturbances (e.g., severe bradycardia 2nd / 3rd degree AV blocks);

- Acute intermittent porphyria

- Poorly controlled epilepsy

- *Due to adrenaline*

- Uncontrolled / severe hypertension
- Severe ischemic heart disease
- Persistent / refractory tachyarrhythmia;
- Thyrotoxicosis;

- Pheochromocytoma.

4.4 Special warnings and precautions for use

Special warning

This product must be used with caution in*:*

Patients with cardiovascular disorders (see section 4.3):
- Peripheral vascular disease;
- Arrhythmias particularly of ventricular origin;
- Heart failure;
- Hypotension.

The product should be administered with caution in patients with impaired cardiac function since they may be less able to compensate changes due to the prolongation of atrio-ventricular conduction.

Patients with epilepsy (see section 4.3):
Because of their convulsive actions, all local anaesthetics should be used very cautiously.

Patients with hepatic disease:
The lowest dose leading to efficient anaesthesia should be used, see section 4.2.

Patients with renal disease:
The lowest dose leading to efficient anaesthesia should be used.

Patients with myasthenia gravis:
The lowest dose leading to efficient anaesthesia should be used.

Patients receiving treatment with antiplatelets / anticoagulants:
The increased risk of severe bleeding after accidental vessel puncture and during oro-maxillo-facial surgery should be considered. INR monitoring should be increased in patients under anticoagulants.

Patients with uncontrolled diabetes:
This product should be used caustiously due to hyperglycemic effect of adrenaline.

Patients with susceptibility of acute angle-closure glaucoma:
This product should be used cautiously due to the presence of adrenaline.

Patients under the influence of illicit drug:
The efficacy of this product may be decreased in these patients.

Elderly patients:
Dosages should be reduced in elderly patients over 70 years old (lack of clinical data).

***The product must be used safely and effectively under appropriate conditions*:**
Adrenaline impairs the flow of blood in the gums, potentially causing local tissue necrosis.
The local anaesthetic effects may be reduced if lidocaine / adrenaline is injected into an inflamed or infected area.

Risk of biting trauma (lips, cheeks, mucosa, and tongue) exists, especially in children; the patient should be told to avoid chewing gum or eating until sensation is restored.

This medicinal product contains potassium metabisulfite, a sulfite which may rarely cause severe hypersensitivity reaction and bronchospasm.

This medicinal product contains less than 1 mmol potassium (39mg) per cartridge i.e it is considered as essentially

"potassium-free".
The product contains less than 1 mmol sodium (23 mg) per cartridge, i.e. it is considered as essentially 'sodium free'.

Precautions for use

Before using this medicinal product, it is important:
-To make inquiries into the patient's diathesis, current therapies and history;
-To maintain verbal contact with the patient;
-Resuscitative equipment should be at hand (see section 4.9).

Risk associated with an accidental intravascular injection:
Accidental intravascular injection (e.g.: inadvertent intravenous injection into the systemic circulation, inadvertent intravenous or intra-arterial injection in the head area and neck area) may be associated with severe adverse reactions, e.g., 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 or conditions of use which may contribute to induce a systemic passage of adrenaline e.g. an administered dose higher than recommended or in case of an accidental intravascular injection.
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 the other medicinal products may require thorough monitoring (See section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Due to the presence of lidocaine

Interactions requiring precautions for use

Additive interactions with other local anaesthetics
Toxicity of local anaesthetics is additive.
This point is considered as not relevant with regard to dental anaesthesia doses and blood levels in adults, but it is a concern in children.
The total dose of administered lidocaine should not exceed the maximum recommended dose.

Opioid sedatives (central nervous system depressants)
Reduced doses of this product should be used due to potential additive CNS effects of lidocaine and sedatives

Inhibitors of metabolism *(e.g. cimetidine)*
Increased serum levels of amide anaesthetics have been reported after concomitant administration of cimetidine.

Non-selective beta-adrenergic blockers (e.g., propranolol, nadolol)
Reduced doses of this product should be used due to possible increase in blood pressure.

Close cardiovascular monitoring is recommended.

Due to the presence of adrenaline

Interactions that are not recommended

Postganglionic adrenergic blocking agents (e.g., guanadrel, guanethidine and rauwolfia alkaloids): Reduced dose of this product should be used under strict medical supervision followed by careful aspiration due to possible increase response to adrenergic vasoconstrictors: risk of hypertension and other cardiovascular effects.

Interactions requiring precautions for use

Halogenated volatile anaesthetics (e.g.: halothane):
Reduced doses of this product should be used due to sensitization of the heart to the arrhythmogenic effects of catecholamines: risk of severe ventricular arrhythmias.

Non-selective beta-adrenergic blockers **(**e.g., propranolol, nadolol):
Reduced doses of this product should be used due to possible increase in blood pressure.
Close cardiovascular monitoring is recommended.

(TCAs) Tricyclic antidepressants (e.g., amitriptyline, desipramine, imipramine, nortriptyline, maprotiline and protriptyline):
Dose and rate of administration of this product should be reduced due to strengthening of adrenaline activity.
Close cardiovascular monitoring is recommended.

MAO inhibitors *[both A-selective MAO inhibitors* (e.g., brofaromine, moclobemide, toloxatone) *and non-selective MAO inhibitors* (e.g., phenelzine, tranylcypromine, linezolide)]:
Use under strict medical supervision due to possible potentialization of the effects of adrenaline.

(COMT inhibitors) Catechol-O-methyl transferase inhibitors (e.g., entacapone, tolcapone):
Arrhythmias, increased heart rate and blood pressure variations may occur.
Cardiovascular monitoring is recommended.

Drug with combination of adrenergic-serotoninergic effect (e.g. venlafaxine milnacipran, sertraline): Dose and rate of administration of this product should be reduced due to additive or synergistic effects on blood pressure and heart rate.
Cardiovascular monitoring (preferably by ECG) is recommended.

Drugs causing arrhythmias in combination with adrenaline (e.g., antiarrhythmics like digitalis, quinidine):
Dose of administration of this product should be reduced due to additive or synergistic effects on heart rate.
Careful aspiration prior to administration and cardiovascular monitoring (ECG) are recommended.

Ergot-type oxytocic drugs (e.g., methysergide, ergotamine, ergonovine):
Use this product under strict medical supervision due to additive or synergistic increases in blood pressure and/or ischemic response.

Sympathomimetic vasopressors (e.g., mainly cocaine but also amphetamines, phenylephrine, pseudoephedrine, oxymetazoline) ***and other sympathomimetics (***e.g., isoproterenol, levothyroxine, methyldopa, antihistamines (such as chlorpheniramine, diphenhydramine):
Risk of adrenergic toxicity. Reduced doses of this product should be used.
If cocaine has been used within 24 hours, the planned dental treatment should be postponed

Phenothiazines and other neuroleptics:

Use under strict medical supervision and cardiovascular monitoring in case of patients with hypotension due to possible inhibition of adrenaline effect.

4.6 Fertility, pregnancy and lactation

Fertility
No adverse effects on fertility were observed in preclinical studies.

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to lidocaine and adrenaline is negligible. This product can be used during pregnancy.

Breastfeeding
Lidocaine/metabolites are excreted in human milk, but at therapeutic doses of this product no effects on the breastfed newborns/infants are anticipated.

4.7 Effects on ability to drive and use machines

Lidocaine in combination with adrenaline solution may have a 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 4.8). So, patients should not leave the dental office within 30 minutes following the dental procedure.

4.8 Undesirable effects

a) Summary of the safety profile

Adverse reactions following administration of lidocaine / adrenaline are similar to those observed with other amide local anaesthetics / combined with vasoconstrictors. These adverse reactions are, in general, dose-related and may result from high plasma levels caused by overdose, rapid absorption or unintended intra-vascular injection. They may also result from hypersensitivity, idiosyncrasy, or diminished tolerance by the specific patient. Nervous system disorders, cardiac disorders and vascular disorders are the most frequently occurring adverse reactions.

Serious adverse reactions are generally systemic. The presence of adrenaline increases the product's safety profile due to its sympathomimetic effects.

b) Tabulated list of adverse reactions

The reported adverse reactions come from spontaneous reporting, clinical studies and literature.
By convention, frequency of initial signs of CNS or CVS toxicity is considered as rare.
The frequencies classification follows the convention: Very common (≥ 1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very Rare (< 10,000) and "Not known (cannot be estimated from the available data)".

MedDRA system Organ Class	Frequency	Adverse reactions
Infections and infestations	Very rare	Abscess oral Alveolar osteitis
	Not known	Gingivitis
Immune system disorders	Rare	Hypersensitivity
		Anaphylactic / anaphylactoid reactions
Psychiatric disorders	Rare	Confusional state, disorientation Logorrhea
	Very rare	Euphoric mood Anxiety/Nervousness/Agitation/Restlessness
Nervous system disorders	Common	Neuropathy peripheral[3]: Neuralgia (neuropathic pain) Hypoesthesia / numbness[3]

		Dysesthesia, including Dysgeusia (e.g., taste metallic, taste disturbance)[3] Ageusia[3] Headache Dizziness (light headedness) Tremor
	Rare	Deep CNS depression: Loss of consciousness Coma Convulsion[4] (including tonic clonic seizure) Presyncope, syncope Speech disorder (e.g., dysarthria) Balance disorder (disequilibrium syndrome) Somnolence Nystagmus Horner's syndrome IIIrd nerve paralysis (paralysis oculomotor)
	Very rare	Paresthesia (i.e., burning sensation, prickling skin sensation, tingling, with no apparent physical cause)
Eye disorders[5]	Rare	Eyelid ptosis, enophthalmos Diplopia Amaurosis Mydriasis Miosis Visual impairment Vision blurred Accommodation disorder
Ear and labyrinth disorders	Rare	Vertigo
	Very rare	Tinnitus / Hyperacusis
Cardiac disorders	Common	Palpitations Tachycardia
	Very rare	Conduction disorders, Atrioventricular block Bradyarrhythmia Bradycardia
	Very rare	Myocardial depression Cardiac arrest Tachyarrhytmia (including ventricular extrasystoles and ventricular fibrillation)[6] Angina pectoris
Vascular disorders	Common	Hypotension (with possible circulatory collapse) Hypertension Pallor (local, regional, general)
	Very rare	Vasodilatation Vasoconstriction Hot flushes
Respiratory, thoracic and mediastinal disorders	Common	Dyspnoea
	Rare	Bronchospasm / asthma[2]
	Not known	Respiratory depression Apnoea (respiratory arrest) Hypoxia[4](including brain) Hypoventilation Hyperventilation Tachypnoea Bradypnoea Hypercapnia[4]

		Yawning Dysphonia (hoarseness[1]) Wheezing
Gastrointestinal disorders	Common	Hypoesthesia oral (and perioral)[3] Dysesthesia oral (and perioral)
	Uncommon	Nausea Vomiting
	Very rare	Paresthesia oral (and perioral structures) Swelling of lip, gum, tongue[8]
	Not known	Gingival/oral mucosal exfoliation (sloughing)/ulceration/necrosis[7] Dysphagia[1] Stomatitis, glossitis Diarrhoea
Skin and subcutaneous tissue disorders	Uncommon	Rash (eruption) Pruritus (itching)
	Rare	Angioedema[1] (oedema of face / tongue / lip / throat / larynx/ periorbital oedema) Urticaria
	Very rare	Hyperhidrosis Swelling face
Musculoskeletal and connective tissue disorders	Uncommon	Myalgia Arthralgia
	Very rare	Muscle twitching, musculoskeletal stiffness Trismus
General disorders and administration site conditions	Very rare	Pain Injection site pain Fatigue, asthenia (weakness) Feeling cold, Feeling hot, feeling abnormal
	Not known	Chills (shivering) Discomfort Injection site swelling Malaise Pyrexia
Injury, poisoning and procedural complications	Common	Procedural pain (Post procedural pain) Contusion

a) Description of selected adverse reactions

[1] Angioedema include oedema of face / tongue / lip / throat / larynx / periorbital oedema. Laryngo-pharyngeal oedema may characteristically occur with hoarseness and / or dysphagia ;

[2] Bronchospasm (bronchoconstriction) may characteristically occur with dyspnoea;

[3] These neural pathologies may occur with the various symptoms of abnormal sensations (i.e., paraesthesia, hypoesthesia, dysesthesia, hyperesthesia, etc.) of the lips, tongue, and oral tissues.

[4] Hypoxia and hypercapnia are secondary to respiratory depression and / or to seizures and sustained muscular exertion;

[5] These neurally mediated effects are due to the presence of local anaesthetic / vasoconstrictor at excessive concentrations regionally or in the systemic circulation;

[6] This mostly occurs in patients with underlying cardiac disease or those receiving certain drugs (section 4.5);

[7] This is due to excessive local effect of the vasoconstrictor;

[8] This occurs by accidental biting or chewing of the lips or tongue while the anaesthesia persists

Because of the presence of adrenaline, precautions and monitoring should be enhanced in the following situations:

patients stressed prior to 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.

b) Paediatric population

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions preferably through the online reporting option accessible from the IMB homepage. A downloadable report form is also accessible from the IMB website, which may be completed manually and submitted to the IMB via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie ,e-mail: medsafety@hpra.ie

4.9 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, respiratory, and finally cardiac toxicity (detailed in section 4.8).

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N01 BB 52
Lidocaine hydrochloride is the anaesthetic agent in the formula. It stabilizes the neuronal membrane and prevents the initiation and transmission of nerve impulses, thereby effecting anaesthesia.

The presence of adrenaline tartrate, a vasoconstrictor in Lignospan Special has the effect of retaining the anaesthetic at the site of injection; this reduces the rate of elimination, through absorption, of lidocaine hydrochloride, thus prolonging the duration of the local anaesthetic action.

5.2 Pharmacokinetic properties

Information derived from diverse formulations, concentrations and usages reveals that lidocaine is completely absorbed following parenteral administration.

Its rate of absorption depending for example, upon various factors such as the site of administration and the presence or absence of a vasoconstrictor agent.

The plasma binding of lidocaine is dependent on drug concentration and the fraction bound decreases with increasing concentration; at concentration of 1 to 4 micrograms of free base per ml, 60 to 80% of lidocaine is protein bound.

Binding is also dependent on the plasma concentration of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood brain and placental barriers presumably by passive diffusion.

Lidocaine is metabolised rapidly by the liver, and metabolites and unchanged drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage, and conjugation. N-dealkylation, a major pathway of biotransformation, yields the metabolites monoethylglycinexylidide and glycinexylidide.

The pharmacological and toxicological actions of these metabolites are similar to, but less potent than, those of lidocaine. Approximately 90% of lidocaine administered is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2, 6-dimethylaniline. Because of the rapid rate at which lidocaine is metabolised, any condition that affects liver function may alter lidocaine kinetics. The half-life may be prolonged two-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6 microgram free base per ml. In the rhesus monkey, arterial blood levels of 18 to 21 micrograms/ml have been shown to be threshold for convulsive activity.

Absorption of adrenaline from subcutaneous tissues occurs slowly because of local vasoconstriction.

Adrenaline is rapidly inactivated in the body despite its stability in the blood.

The liver, which is rich in both of the enzymes responsible for the destruction of circulating adrenaline (COMT and MAO), is an important tissue in the degradation process.

The greater part of a dose of Adrenaline injected into man is excreted as metabolites in the urine (GOODMAN and GILMAN'S).

Adrenaline tartrate has the effect of prolonging the localisation of the anaesthetic at the site of the injection.

From the information quoted beforehand, it can be concluded that in Lignospan Special solution, the presence of the vasoconstrictor slows down the absorption, and therefore the metabolism of lidocaine.

5.3 Preclinical safety data

Acute and subacute toxicity studies

- Lidocaine
The LD50 of IV lidocaine is 20-46, 18-20 and 26-41 mg/kg in mouse, rat and rabbit respectively. Acute toxicity is highly reduced when the drug is injected subcutaneously (LD50 in mouse and rat: 192-400 and 335 mg/kg respectively). The cause of death is respiratory arrest that is preceded by convulsions.

In rats, concomitant IV administration of adrenaline was found to decrease the LD_{50} of lidocaine by a 1.8 fold extent (11.4 versus 20.1 mg/kg).

- Adrenaline
The LD50 of adrenaline by subcutaneous administration is 5 mg/kg in rat and dog. When administered intravenously, the LD50 is 0.1 mg/kg in dog.

Effect on reproduction and teratogenicity studies

The studies one may conclude that lidocaine is devoid of teratogenic effect and of deleterious effect on reproduction, in rats.

Mutagenicity and carcinogenicity studies

The mutagenic potential of lidocaine has not been determined. Long-term studies with local anaesthetics (including lidocaine) have not been conducted to evaluate the carcinogenic potential due to short term administration in humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium metabisulphite (E224)
Disodium edetate
Sodium hydroxide solution (for pH adjustment)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light.
Do not freeze.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Use on one patient during one session of treatment only. If only part is used the remainder must be discarded in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

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