Children
This product should not be used in children under age 4, because the risk of efficacy and safety concerns.

Other medicines and Anestadent™ 4% w/v and 1:100,000
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Anestadent™ 4% w/v and 1:100,000 can affect the way some other medicines work. Also some other medicines can affect the way this medicine works.

Precautions for use under strict medical supervision are required:
- all classes of antidepressant medicines: monoamine oxidase inhibitors or MAOIs (proniazide, moclobemide, toloxatone), tricyclic antidepressants (imipramine, amoxapine, amitriptyline, desipramine, nortriptyline), serotonergics and noradrennergics (milnacipran and venlafaxine)
- halogenated volatile anaesthetics (isoflurane, desflurane)
- medicines which affect the way your heart beats called ‘non-selective beta-blockers’ such as propanolol. If you are given Anestadent™ 4% w/v and 1:100,000 when taking a ‘beta-blocker’ you may get very high blood pressure or a very slow heart rate
- guanethidine and related medicines, used to treat glaucoma

If any of the above apply to you (or you are not sure), talk to your dentist or doctor before using this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You are pregnant, as a precautionary measure, it is preferable to avoid the use of Anestadent™ 4% w/v and 1:100,000.

If you are breast-feeding, you can use Anestadent™ 4% w/v and 1:100,000 if necessary.

Driving and using machines
Talk to your dentist or doctor before driving or using any tools or machines. They will tell you when it is safe to do these activities again after your dental work.

Anestadent™ 4% w/v and 1:100,000 contains sodium and metabisulphite
This medicinal product contains less than 1 mmol sodium (23 mg) per cartridge, i.e. essentially ‘sodium-free’. Due to the presence of sodium metabisulphite, it may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to use Anestadent™ 4% w/v and 1:100,000
How much Anestadent™ 4% w/v and 1:100,000 you will be given
Your dentist or doctor will give you Anestadent™ 4% w/v and 1:100,000 according to:
- The dentist or doctor will decide how much of this medicine to give you.
- The dose will depend on what it is being used for and also on other factors, such as your health, age and weight.
- The smallest possible dose will be used.
- The maximum dose for adults is 7 mg per kilogram of body weight.

The quantity to be injected will be adjusted according to the extent of the procedure.
As a general rule, one to three cartridges per session.

Use in children (4 years and older)
The dose depends on the child’s age and weight and the type of procedure being conducted. The maximum dose is 5 mg of articaine hydrochloride per kilogram of body weight.

The mean dose in mg of articaine hydrochloride that can be administered in children may be calculated as follows:
Child’s weight (in kilograms) x 1.33.

Do not use in children younger than 4 years old.

Elderly
Reduce the adult dosage by half.
Route and method of administration
The medicinal product is for dental use and will be administered to you as an injection into your oral cavity by the dentist.

Injection rate should not exceed 1 mL of solution per minute.

Method of use, handling instructions (for the doctor)
As with any cartridge, the diaphragm should be disinfected just before use. It should be carefully swabbed:
• either with 70% ethyl alcohol, or with 90% pure isopropyl alcohol for pharmaceutical use.

The cartridges must never be immersed in any solution whatsoever. Do not mix the solution for injection in the same syringe with other products. Previously used anesthetic solution cartridges must not be reused.

Duration of treatment
Single use.

If you use more Anestadent™ 4% w/v and 1:100,000 than you should
It is unlikely that you will be given too much of this medicine, as it will be given by a dentist or doctor.

If you think you have been given too much, tell your dentist or doctor immediately.

The following effects may happen:
• feeling confused, fear, breathing quickly (tachyypnoea), an increase in blood pressure and face blushing, feeling or being sick, tremors, spasms (including in your jaw), having a fit (convulsion)
• a feeling the room is spinning (vertigo), not being able to speak, hearing problems, loss of consciousness, muscle contractions, problems controlling the size of blood vessels (vascular-motor complications), breathing problems including stopping breathing, death
• slow heart beat (bradycardia), uneven heart beat (arrhythmia), rapid and chaotic heart beat (fibrillation), low blood pressure (hypotension), heart stopping (cardiac arrest), blue skin colour (cyanosis)

If you have any further questions on the use of this product, ask your dentist, doctor or pharmacist.

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

The following side effects may happen. If you notice any of the following possible side effects see your dentist or doctor straight away:

Rare (affects less than 1 in 1,000 people)
• slow heartbeat (bradycardia)
• uneven heart beat (arrhythmia)
• excitationary reactions, tremors, feeling disoriented, taste of metal in mouth, a feeling the room is spinning (vertigo), a ringing or other noise in the ears (tinnitus), widening of the pupil (mydriasis), pins and needles (paraesthesia), jaw spasms and convulsions (conclusion)
• eye problems (such as double vision) which usually go away
• rapid breathing (tachypnoea), widening of air passages (bronchodilation)
• feeling or being sick
• increase in your metabolism
• low or high blood pressure (hypotension or hypertension)
• increase in body temperature
• feeling nervous (anxiety), pain in your throat or behind your breastbone, heat sensation, sweating, headache

Very rare (affects less than 1 in 10,000 people)
• skin rash, itching (pruritus), itchy skin rash often with raised lumps (urticaria)
• allergic reactions (which can range from problems breathing and swelling of the tube which transfers air to the lungs (larynx) up to cardiorespiratory collapse from anaphylactic shock)

As the product contains sodium metabisulphite, it may rarely cause severe allergic reaction and problems breathing (bronchospasm).

If this medicine is accidently injected into blood vessels it can cause lack of blood flow where it is injected. This can sometimes progress to death of the tissue (tissue necrosis).

Lesions to nerves, hyposensitivy and alterations of taste, may occur after an incorrect injection or in case of patient with particular conditions.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Anestadent™ 4% w/v and 1:100,000
Keep this medicine out of the sight and reach of children.

This medicine should be kept at a temperature below 30°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any 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 Anestadent™ 4% w/v and 1:100,000 contains
• The active substances are:
  Articaine hydrochloride......................... 40.00 mg/mL
  Adrenaline tartrate
  Sodium chloride
• The other ingredients are:
  Sodium metabisulphite
  Hydrochloric acid
  Sodium hydroxide
  Water for injection

What Anestadent™ 4% w/v and 1:100,000 looks like and contents of the pack
This medicine is in the form of a solution for injection.

Box of 50 cartridges of 1.8 mL with self-aspiring stopper
Box of 50 cartridges of 2.2 mL with standard stopper
Box of 50 cartridges of 2.2 mL with standard stopper

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
DENSPFLY Limited
Building 3, The Heights
Weybridge, Surrey, KT13 0NY
United Kingdom

Manufacturer
Laboratorios INIBSA S.A.
Ctra. Sabadel a Granollers, Km 14,5
Lleí de Vall (Barcelona) 08185
Spain

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