Local Anesthetics
Solution for Injection

Targeting improved comfort
With our 50 years of solid experience in the development and manufacture of local anaesthetics, you can be sure of making the right choice.

3M ESPE Local Anaesthetics – Making the right choice can be so easy

The benefits for your patients: effective and generally easily tolerated products for local pain control.

3M ESPE offers you a choice of effective, generally easily tolerated local anaesthetics:

1. Ubistesin™ 1/200 000 solution for injection – for routine-type interventions.

2. Ubistesin™ 1/100 000 solution for injection – for more complex interventions requiring prolonged anaesthesia.


The benefits for your practice: an ingenious packaging system.

1. Cylindrical glass ampoules with inner coating of silicon.
   - Smooth, gentle, controlled injection.
   - Smoother gliding of the stopper.
   - Less force required for injection and, more importantly, less initial resistance.

2. Safety foil instead of direct pressure on the glass.
   - Protection from of splinters if the ampoule breaks (comparable to the laminated glass used in car windshields).
   - Especially important for intraligamental anaesthesia, where particularly high stresses are applied.

3. Packaged in a solid metal storage tin with a padded interior.
   - Protection against damage during shipping.
   - Easy to remove.
   - Simple to store neatly.
   - Simple and ecological recycling.

Pluraject™

Aspiration syringe for cylindrical glass ampoules with perforated stoppers.

- Easy handling
- Good aspiration
- Innovative square head reduces malfunction and wear

All 50 ampoules in this tin were intact.
Ubistesin™ 1/200 000 – for routine-type interventions.

- Contains 4% Articaine with Adrenaline 1/200 000 as a vasoconstrictor.
- Contains only Sulphite as a stabilizer.
- Suitable for adults and children over the age of 4 years.
- Average duration of action: 45 minutes, with an onset period of 1–3 minutes.

Ubistesin™ 1/100 000 – for more complex interventions requiring prolonged anaesthesia.

- Contains 4% Articaine and Adrenaline 1/100 000 as a vasoconstrictor.
- Contains only Sulphite as a stabilizer.
- Suitable for adults and children over the age of 4 years.
- Average duration of action: 75 minutes, with an onset period of 1–3 minutes.

Mepivastesin™ – for simple, routine-type interventions in risk patients.

- Contains 3% Mepivacaine.
- Contains no further additives and no Adrenaline; thus, it is particularly suited for patients suffering from circulatory lability with a contraindication for vasoconstrictive additives.
- Suitable for adults and children over the age of 4 years.
- Average duration of action: 20 minutes, with an onset period of 2–4 minutes.
Local Anesthetics

Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 solution for injection

COMPOSITION
Active substance: Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000
1 ml solution for injection contains:
- Active substances:
  - Articaine hydrochloride 40 mg
  - Adrenaline hydrochloride 0.006 mg (corresponding to 10 µg adrenaline (epinephrine))
- Excipients:
  - Sodium sulphite max. 0.6 mg (equivalent to max. 0.31 mg SO2)
  - Sodium chloride, Water for injections, Hydrochloric acid and sodiumhydroxide solution for adjusting the pH-value

Ubistesin™ 1/200 000
1 ml solution for injection contains:
- Active substances:
  - Articaine hydrochloride 40 mg
  - Adrenaline hydrochloride 0.006 mg (corresponding to 10 µg adrenaline (epinephrine))
- Excipients:
  - Sodium sulphite max. 0.6 mg (equivalent to max. 0.31 mg SO2)
  - Sodium chloride, Water for injections, Hydrochloric acid and sodiumhydroxide solution for adjusting the pH-value

Ubistesin™ 1/100 000
1 ml solution for injection contains:
- Active substances:
  - Articaine hydrochloride 40 mg
  - Adrenaline hydrochloride 0.006 mg (corresponding to 10 µg adrenaline (epinephrine))
- Excipients:
  - Sodium sulphite max. 0.6 mg (equivalent to max. 0.31 mg SO2)
  - Sodium chloride, Water for injections, Hydrochloric acid and sodiumhydroxide solution for adjusting the pH-value

CLINICAL PARTICULARS
Therapeutic indications
Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 is indicated for local anaesthesia and nerve-block anaesthesia in dentistry during minor procedures.

Ubistesin™ 1/100 000 is especially indicated for complicated procedures requiring prolonged anaesthesia.

Contraindications
The use in children under 4 years of age is contraindicated.

Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 is contraindicated in case of hypersensitivity to any of the components.

Due to the local anaesthetic ingredient articaine, Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 is not allowed to be used in the event of:
- Known allergy or hypersensitivity to local anaesthetics of the amide type
- Severe impairment of the impulsiion initiation and conduction system of the heart (e.g. grade II and III AV block, pronounced bradycardia)
- Acutely decompenated cardiac insufficiency
- Severe hypotension
- Patients who are known to have a deficiency in plasma cholinesterase activity
- Haemorrhagic diathesis – particularly with nerve-block anesthesia
- Injection into an inflamed area

Due to the content of adrenaline (epinephrine), Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 is not allowed to be used in the event of:
- Heart diseases such as:
  - Unstable angina pectoris
  - Recent myocardial infarction
  - Recent coronary artery bypass surgery
  - Refractory arrhythmias and paroxysmal tachycardia or high-frequency, cardiovagal arrhythmia
  - Untreated or uncontrolled severe hypertension
  - Untreated or uncontrolled congestive heart failure

Concomitant treatment with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants

Due to the content of sulphite as excipient, Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 is not allowed to be used in the event of:
- Severe bronchial asthma

Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 can provoke acute allergic reactions with anaphylactic symptoms (e.g. bronchoconstriction).

Special warnings and precautions for use
Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 must be used with particular caution in the event of:
- Severe impairment of the renal function
- Angina pectoris
- Arteriosclerosis
- Considerably impaired blood coagulation
- Thyrotoxicosis
- Narrow-angle glaucoma
- Diabetes mellitus
- Lung diseases – particularly allergic asthma
- Pheochromocytoma

Accidental injection may be associated with convulsions, followed by central nervous system or cardiopulmonary arrest. Resuscitative equipment, oxygen, and other resuscitative drugs should be available for immediate use.

Since amide-type local anaesthetics are also metabolised by the liver, Ubistesin™ 1/200 000 / Ubistesin™ 1/100 000 should be used with caution in patients with hepatic diseases. Patients with severe hepatic diseases are at greater risk of developing toxic plasma concentrations.

The product should be administered with caution in patients with impaired cardiovascular function since they may be less able to compensate for cerebral blood flow loss associated with the prolongation of A-V conduction produced by these drugs.

The product should be administered with caution for patients with a history of epilepsy.

There is a possibility of positive results in doping tests performed on sportsmen.

It should be taken into consideration that during treatment with blood coagulation inhibitors (e.g. heparin or acetylsalicylic acid), an inadvertent vasopuncture when administering the local anaesthetic can lead to serious bleeding, and that in general the hemorrhagic tendency is increased.

Inadvertent intravascular application must be avoided.

The lower blood flow in the pulp tissue due to the content of adrenaline (epinephrine) and thus the risk to overlook an opened pulp has to be taken into account regarding cavity or crown preparations.

Precautions for use:
Each time a local anaesthetic is used the following drugs/therapy should be available:
- Anti-convulsant medicines (benzodiazepines or barbiturates), musclerelaxants, atropine and vasoressors or adrenaline for a severe allergic or anaphylactic reaction.
- Resuscitation equipment (in particular a source of oxygen) enabling artificial ventilation if necessary.
- Careful and constant monitoring of cardiovascular and respiratory (axedency of ventilation) vital signs and the patient’s state of consciousness should be monitored after each local anaesthetic injection.
- Respiratory distress, anxiety, tinnitus, dizziness, blurred vision, tremors, depression, or drowsiness may be early warning signs of central nervous system toxicity.

Patients taking phenothiazines
Promethazine may reduce or even reverse the pressor effect of adrenaline (epinephrine). Concurrent use of these agents should generally be avoided.

Patients taking non-selective beta-blockers
The concomitant administration of non-cardioselective beta-blockers can lead to an increase in blood pressure due to adrenaline (epinephrine).

Pregnancy and lactation
No clinical experience of the use in pregnant and lactating women is available. Safe use of local anaesthetics during pregnancy has not been established with respect to adverse effects on fetal development. This medicine should only be used in pregnancy when the benefits are considered to outweigh the risks.

The excretion of articaine and its metabolites in human milk is unknown. However, preclinical safety data suggest that the concentration of articaine in breast milk does not reach clinically relevant concentrations. Therefore, nursing mothers should milk and discard the first milk after following anaesthesia with articaine.

The benefits are considered to outweigh the risks.

No clinical experience of the use in pregnant and lactating women is available.

When these signs appear are required rapid corrective measures to prevent possible worsening.

Dizziness, confusion, muscle twitching, toxic- CNS seizures, coma and respiratory paralysis.

Respiratory disorders
Rare (≤ 0.01%)
Tachypnea, then bradypnea, which could lead to apnoea.

Allergic reactions
Very rare (< 0.001%)
One may observe manifestation of hypersensitivity to articaine as rash, pruritus, urticaria, erythema and as nausea, diarrhoea, wheezing or anaphylaxis. Cross-reactivity to articaine has been reported in a patient with delayed hypersensitivity to procaine.

In general, patients with demonstrated hypersensitivity to articaine or other amidé should receive an ester-group local anaesthetic for subsequent procedures.

The administration of large doses of articaine may produce methaemoglobinemia in patients with subclinical methaemoglobinemia.

Due to the content of adrenaline (epinephrine) as a vasoconstrictor, the following undesirable effects can occur:

Cardiovascular disorders
Rare (≤ 0.01%)
Heat sensation, sweating, heart racing, migraine-like headache, blood pressure increase, angina pectoris disorder, tachycardia, tachyarrhythmias and cardiovascular arrest as well as acute oedematous thyroid swelling cannot be ruled out.

Due to the content of sulphite as excipient, the following undesirable effects can occur:

Nervous system disorders
2 weeks delayed onset of facial nerve paralysis has been described with articaine/ adrenaline (epinephrine), the event still occurs 6 months later.

Due to the content of both articaine and adrenaline (epinephrine), the following undesirable effects can occur:

Due to the occurrence of various complications and side effects.

Precaution
Information shortened. For further details please refer to the Instructions for Use.

Date of revision of the text:
August 2002

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