Local Anesthetics

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

COMPOSITION
Active substances:
Articaine hydrochloride 40 mg
Adrenaline hydrochloride 0.006 mg
(corresponding to 5 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
solution for injection contains:
Optimal substances:
Articaine hydrochloride 40 mg
Adrenaline hydrochloride 0.012 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 especially indicated for complicated dentistry.
Ubistesin 1/100 000 is indicated for infiltration 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.

Due to the local anaesthetic ingredientarticaine, Ubistesin 1/200 000 / Ubistesin 1/100 000 is contraindicated in case of hypersensitivity to any of the components.

Due to the local anaesthetic ingredientarticaine, Ubistesin 1/200 000 / Ubistesin 1/100 000 is contrained to be used in the event of:

- known allergy or hypersensitivity to local anaesthetics of the amide type
- severe impairment of the immune 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 anaesthesia
- injection into an inflamed area

Due to the content of adrenaline (epinephrine) on a vasococstrictor admixture, Ubistesin 1/200 000 / Ubistesin 1/100 000 is not allowed to be used in the event of:

- 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 hypotension
- untreated or uncontrolled congestive heart failure
- concurrent treatment with monoene oxide (MQ) 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. bronchoconspasm).

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
- narro-se-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. Resuscitation 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 for patients with hepatic diseases. Patients with severe hepatic diseases are at greater risk of developing toxic plasma concentration.

The product should be administered with caution in patients with impaired cardiovascular function since they may be less able to compensate for hormonal changes 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 can 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 vasoconstrictors 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 (adequacy of ventilation) vital signs and the patient’s state of consciousness should be monitored after each local anaesthetic injection.

Due to the content of adrenaline (epinephrine), the event still occurs 6 to 2 weeks delayed onset of facial nerve paralysis has been described.

Effects on the ability to drive and use machines

Although test patients have shown no impairment of their normal reactions when driving a vehicle, the dentist has to assess in each case the possible impairment of safety when operating a motor vehicle or machinery. The patient should not leave the dental office earlier than at least 30 minutes after the injection.

Undesirable effects

Due to the local anaesthetic ingredientarticaine, the following adverse effects can occur:

Cardiovascular disorders

Rare (≤ 0.01%)

- Decrease in heart rate, hypotension.
- Drop in blood pressure, cardiac impulse conduction disorders, bradycardia, asystolia, cardiovascular arrest.

Nervous system disorders

Rare (≤ 0.01%)

- Metalic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, yawning, shaking, nervousness, myalgias, logorrhea, headache, increase in respiratory rate, Paretellamias (loss of sensation, burning, tingling) of the lip, tongue, or both.

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

Dropiness, confusion, muscle twitching, toxic-cyclic seizures, coma and respiratory paralysis.

Respiratory disorders

Rare (≤ 0.01%)

- Tachycardia, then bradycardia, which could lead to apnoea.

Allergic reactions

Very rare (≤ 0.01%)

One may observe manifestation of hypersensitivity to articaine as rash, pruritus, urticaria, erythema and as well 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 amides 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 admixture, the following undesirable effects can occur:

Cardiovascular disorders

Rare (≤ 0.01%)

- Heat sensation, sweading, heart racing, migraine-like headache, blood pressure increase, angina pectoris disorders, 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:

- Allergic reactions or hypersensitivity reactions, particularly in bronchial asthmatics, which are manifested as vomiting, diarrhoea, wheezing, acute asthma attack, clauding of consciousness or shock.

Due to the content of both articaine and adrenaline (epinephrine), 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.

Interferences in the clinical picture can result from the simultaneous occurrence of various complications and side effects.

Prescription

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

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Local anesthetics for your patients

Competence & precision you can trust

Local Anesthetics Solutions
Ubistesin™ – the local anesthetic. Dose as needed, where it’s needed.

Anesthesia is like sports: with experience and pinpointed concentration, you get your best results. A steady hand, a sure eye and the precise use of all medicines go a very long way towards minimising the stress to your patients during interventions. As a proven local anesthetic, Ubistesin™, helps hone your expertise during anesthesia.

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 anesthetics:

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 anesthesia.

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 anesthesia, 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.

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 anesthesia.**

- 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.

**Pluraject™**

Aspiration syringe for cylindrical glass ampoules with perforated stoppers.

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