Solutions for Injection

3M™ ESPE™ Ubistesin™

Articaine HCl 4% & Adrenaline 1:200 000

3M™ ESPE™ Ubistesin™ Forte

Articaine HCl 4% & Adrenaline 1:100 000

The precise solution for any application

25 Years of Ubistesin™

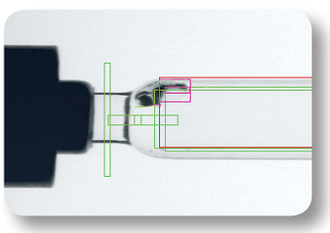
3M ESPE

3M™ ESPE™ Ubistesin™
Competence You Can Trust

With Ubistesin, you can rely on an effective and well-tolerated compound that has proven itself millions of times in dental practice. Behind it stand more than 50 years of experience in the development of local anaesthetics – leading-edge know-how, which you and your patients can trust. 3M ESPE has been awarded the most innovative dental company* seven times in a row and is dedicated to the highest possible standards – expressed in the label “Made in Germany”.

* The Anaheim Group

Proven Manufacturing



How is the high quality of 3M ESPE local anaesthetics checked and safeguarded?

We bank on a double quality assurance: First, the washed and siliconized cartridges are filled by means of a laser-controlled process. This step guarantees a particularly high degree of freedom from bubbles. As an additional step, all cartridges pass through an optoelectronic control system to check them for visible particles in the solution, absence of bubbles, potential glass defects, correct position and size of stopper. Cartridges that do not meet the predetermined parameters are separated out and discarded. By this means, cartridges with air bubbles, for example, are prevented from being sold.

Smart packaging – safe handling.

Even the packaging has been continuously refined. With a series of well-thought-out features, it is now more convenient than ever:

- Cylindrical glass ampoules with inner silicone coating – for a smooth, gentle and controlled injection
- Safety foil – prevents splintering
- Packaging in a stable metal box with a padded interior – for safe transport, easy removal and tidy storage
- Colour-coded aluminium caps – No chance of mix-ups!

Ubistesin™ 1/200 000  **Red**

Ubistesin™ Forte 1/100 000  **Gold**

3M ESPE
A Brand you can Trust

Articaine - Supported by 30 years of clinical history

Ubistesin provides profound anaesthesia

Rapid metabolism and high plasma protein binding allows for a 4% articaine[1] formulation resulting in profound anaesthesia being achieved by Ubistesin. Higher efficacy[2,3] enables possible decrease in volume and lower epinephrine concentration 1:200.000 for routine dental procedures.

Supporting Abstracts

Articaine's rapid metabolism and high plasma protein binding results in low overall systemic toxicity. This allows its use in dentistry in the form of a 4% solution.

1. Rahn R, Oertel R, Richter K, Kirch W, Lemmer B, Niehaus C: Serum Concentration of Articaine in Repeated Submucosal Injection of a 4% Vasoconstrictor-free Solution DZZ 1996; 51: 399

Supporting Abstract

A meta-analysis in 2010 proves the higher local anesthetic efficacy of articaine over lidocaine

2. Katyal V. The efficacy and safety of articaine versus lidocaine in dental treatments: a meta-analysis:J Dent. 2010 Apr; 38(4): 307-17. Epub 2009 Dec 16

Supporting Abstract

A further meta-analysis covered 1146 patients and 1395 local anesthesia in randomized clinical studies. The results show a 9.21% higher success rate of articaine in comparision to lidocaine and confirmed a better efficacy of articaine over lidocaine

3. Paxton Kellie, Thome David, Efficacy of Articaine Formulations: Quantitative Reviews Dent Clin N Am 54 (2010) 643-653.

Ubistesin provides the least risk anaesthetic for your patients

High plasma binding rates leading to low systematic toxicity[1] and shortest elimination half-time makes Ubistesin the least risk anaesthetic for the majority of patients.

Supporting Abstracts

Cerebral toxicity is low and only 25% of the articaine dose reaches the foetus.

1. Daublander, Monika, Journal of the Irish Dental Association, volume 57, Oct-Nov 2011.

Physico-chemical & pharmacological properties of Local Anaesthetics

- High lipid solubility = Increased potency of anaesthetic
- High protein binding rate = Duration of action is increased
- Efficient metabolism = Lower toxicity, more rapid inactivation of active
- Shorter elimination half-time = more efficient removal of active from the blood

Local Anaesthetic agents – Physico-chemical and pharmacological properties

	Articaine	Lidocaine	Mepivacaine	Prilocaine
Lipid Solubility	High	Medium	Medium	Medium
Protein Binding Rate	95%	65%	75%	55%
Metabolic process	Liver & Plasma	Liver	Liver	Liver
Elimination Half Time (Hours)	20mins	90mins	114mins	93min

Borchard U, 1985, Catterall 2001, Derendorf H et al, 1987 Malamed SB, 2004; Oertel R et al, 1997; USP DI, 2004

A better choice
for you and your patients

3M™ ESPE™ Ubistesin™ 1/200 000

for routine procedures

- Contains 4 % articaine and adrenaline 1/200 000 as a vasoconstrictor
- Contains only Sulphite as a stabiliser
- For adults and children aged 4 and over
- Average duration of action:
  - · Pulp anaesthesia: approx. 45 minutes
  - · Soft-tissue anaesthesia: 120–240 minutes
  - · Onset period of 1–3 minutes

3M™ ESPE™ Ubistesin™ Forte 1/100 000

for complicated procedures requiring prolonged anaesthesia

- Contains 4 % articaine and adrenaline 1/100 000 as a vasoconstrictor
- Contains only Sulphite as a stabiliser
- For adults and children aged 4 and over
- Average duration of action:
  - · Pulp anaesthesia: approx. 75 minutes
  - · Soft-tissue anaesthesia: > 240 minutes
  - · Onset period of 1–3 minutes

with **4%** Articaine

» Predictable » Profound » Anaesthesia

Cartridge size

3M ESPE Ubistesin: a precise solution for all applications.

Ubistesin is a high efficacy solution available in a 1.8ml size glass cartridge (volume of injectable solution is 1.7ml) that conforms to clinical dosage recommendations.

(*Handbook of Local Anaesthesia 5th Edition, 2004 (Elsevier Mosby) *Stanley F. Malamed* Chapter 4, Table 4.4, page 58)

3M™ ESPE™ Pluraject™ 2 aspirating syringe

for cylindrical glass cartridges with perforated stoppers

- Compact and lightweight for better handling
- Cartridges are easy to insert and remove thanks to the hinge mechanism
- Appropriate for both active and passive aspiration
- Compatible with 1.8 mL cartridge

Competence you can trust

Local Anaesthetics

Summary of Product Characteristics

UBISTESIN™ 1/100 000, 40 mg/ml + 10 micrograms/ml, solution for injection; Ubistesin™ 1/200 000, 40 mg/ml + 5 micrograms/ml, solution for injection; **COMPOSITION:** Ubistesin 1/100 000, 1 ml solution for injection contains: *Active substances* Articaine hydrochloride 40 mg, Epinephrine (Adrenaline) 10 micrograms (as hydrochloride); Ubistesin 1/200 000, 1 ml solution for injection contains: *Active substances* Articaine hydrochloride 40 mg, Epinephrine (Adrenaline) 5 micrograms (as hydrochloride); **THERAPEUTIC INDICATIONS:** Ubistesin 1/100 000, local anaesthesia (infiltration and nerve block anaesthesia) in dentistry. Ubistesin 1/100 000 is especially indicated for complicated procedures requiring prolonged anaesthesia. Ubistesin 1/200 000, Local anaesthesia (infiltration and nerve block anaesthesia) in dentistry during minor procedures. **CONTRAINDICATIONS:** Ubistesin must not be used in children under 4 years of age (< 20 kg), patients with (a history of) hypersensitivity to the active substances, sodium sulphite (E221) or to any of the other excipients, patients with haemorrhagic diatheses – increased bleeding risk particularly with nerve block anaesthesia, due to the local anaesthetic ingredient articaine, Ubistesin must not be used in the event of known allergy or hypersensitivity to local anaesthetics of the amide type, patients who are known to have a deficiency in plasma cholinesterase activity, also drug-induced forms, severe, uncontrolled or untreated excitation and conduction disorders of the heart (e.g. grade II and III AV block, pronounced bradycardia), acutely decompensated heart failure, severe hypotension, injection into an inflamed area because of treatment failure due to reduced penetration of articaine into the inflamed area. Due to the content of epinephrine as a vasoconstrictor admixture, Ubistesin must not 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, continuous arrhythmia, untreated or uncontrolled severe hypertension, untreated or uncontrolled congestive heart failure, concomitant treatment with monoamine oxidase (MAO) inhibitors or tricyclic antidepressants. Ubistesin is not allowed to be used in acra of extremities. Due to the content of sulphite as excipient, Ubistesin must not be used in the event of allergy or hypersensitivity to sulphite, severe bronchial asthma. Ubistesin can provoke acute allergic reactions with anaphylactic symptoms (e.g. bronchospasm). **UNDESIRABLE EFFECTS:** Due to the local anaesthetic ingredient articaine, the following adverse effects can occur: CARDIOVASCULAR DISORDERS: *Rare* (>1/10 000 to < 1/1 000), decrease in heart rate, hypotension. Drop in blood pressure, cardiac impulse conduction disorders, bradycardia, asystolia, cardiovascular arrest. NERVOUS SYSTEM DISORDERS: *Rare* (>1/10 000 to < 1/1 000), metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, yawning, shaking, nervousness, nystagmus, logorrhoea, headache, increase in respiratory rate. Paresthesias (loss of sensation, burning, tingling) of the lip, tongue, or both. When the following signs appear, rapid corrective measures are required to prevent possible worsening: Drowsiness, confusion, tremor, muscle twitching, tonic-clonic seizures, coma and respiratory paralysis. RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS: *Rare* (>1/10 000 to < 1/1 000), Tachypnea, then bradypnea, which could lead to apnoea. ALLERGIC REACTIONS: V*ery rare* (< 1/10 000), one may observe manifestation of hypersensitivity to articaine as rash, pruritus edema, pruritus and erythema as well as nausea, diarrhea, wheezing or anaphylaxis. The administration of large doses of articaine may produce methaemoglobinemia in patients with subclinical methaemoglobinemia. Due to the content of epinephrine as a vasoconstrictor admixture, the following undesirable effects can occur: CARDIOVASCULAR DISORDERS: *Rare* (>1/10,000 to < 1/1 000) heat sensation, sweating, heart racing, migrainelike headache, blood pressure increase, angina pectoris disorders, tachycardias, tachyarrhythmias and cardiovascular arrest as well as acute oedematous thyroid swelling. Due to the content of sulphite as excipient, the following undesirable effects can occur in very rare cases: Allergic reactions or hypersensitivity reactions, particularly in bronchial asthmatics, which are manifested as vomiting, diarrhoea, wheezing, acute asthma attack, clouding of consciousness or shock. Prescription, information shortened.

Please review the **Product Information** before administering the product.

PBS information: This Product is not listed on the PBS.

3M Australia Pty Limited

3M Health Care Group
3M ESPE Dental Division
Building A, 1 Rivett Rd
North Ryde, NSW 2113
ABN 90 000 100 096
Ph: 1300 363 454
www.3MESPE.com.au

www.3MESPE.com.au

PB6813/0514