
PIERREL
Italian quality and innovation
for oral health

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Founded in 1948, Pierrel is an Italian pharmaceutical company based in Capua, specializing in the development, production, registration, and licensing of dental anesthetics and medical devices for oral health.

Over the years, Pierrel has focused on producing, registering, and marketing its own line of dental anesthetics. With FDA approval in the U.S., Pierrel has built a strong presence in the American market and is now one of the leading producers of dental anesthetics sold under its own brands: Orabloc, Ubisestin™, Xylestesin™, Mepivastesin™, Piercaine and Lidocaine Pierrel. Today, the company holds over 100 product registrations worldwide.

In addition to anesthetics, Pierrel develops innovative medical devices aimed at improving accessibility for oral health professionals. Through continuous research, the company actively seeks out the best solutions for dentists and collaborates with universities and research institutions worldwide.

A strong intellectual property portfolio, combined with expertise in product development and targeted marketing, strengthens Pierrel's offering with cutting-edge innovations that meet the evolving needs of dental professionals.

PIERREL LOCAL ANAESTHETICS

With Pierrel local anaesthetics, you can rely on an effective and well-tolerated compound that has proven itself millions of times in dental practice. Behind it stands more than 50 years of experience in the development of local anaesthetics – leading-edge know-how, which you and your patients can trust.

Cartridge Size

All Pierrel local anaesthetics come in a 1.8ml size glass cartridge (volume of injectable solution is 1.7ml) - an optimal amount that conforms to clinical dosage recommendations, as per the tables below:

Recommended Volumes for Injection Techniques:*	Technique	Volumes (ml)
Maxillary Injection Techniques	Buccal Infiltration	0.6
	Palatal Infiltration	0.2 to 0.3
Mandibular Injection Techniques	Mandibular Nerve Block	1.5
	Buccal Infiltration	0.6
	Long Buccal Nerve Block	0.3
	Intraligamental	0.3

*Malamed SF, 2004. Handbook of local anaesthesia 5th Ed. (pages 224, 253 & 258) - The smallest possible volume of solution that will lead to effective anaesthesia should be used. The maximum recommended dosage should not be exceeded. Please refer to the local anaesthetic product datasheet for dosage, warnings and precautions.

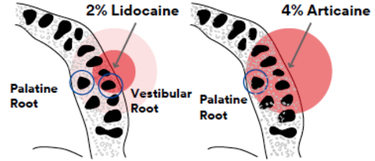
Local anaesthetic agents – Physico-chemical and pharmacological properties			
	Articaine	**Lidocaine**	**Mepivacaine**
Lipid Solubility	high	medium	medium
Protein-Binding-Rate	94 %	77 %	78 %
Rel. Potency*	5	4	4
Rel. Toxicity*	1.5	2	2
Ratio - Potency:Toxicity	3.3	2	2
Elimination Half Time	20 min	90 min	114 min

* Procaine = 1

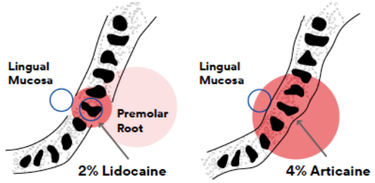
Reference: Pilz G: Klinische Vergleichsstudie zur Wirkung von Articain and Lidocain. In Frenkel G (Hrsg.): Symposium 20 Jahre Ultracain® . Aktuelles Wissen Hoechst 1998

Clinical efficacy of local anaesthetic solutions and concentrations

Maxillary Molar Extraction



Mandibular Molar Extraction



DENTAL ANESTHESIA

Ubistesin 1:400,000
For minor procedures

Properties
- 4 % articaine and epinephrine (adrenaline) 1/400 000 as a vasoconstrictor
- Indications: Infiltration and nerve-block anaesthesia for routine procedures lasting up to 30 minutes
- Only sulfite as a stabilizer
- Appropriate for adults and children aged 4 and over
- Average duration of action:
  Pulpal anaesthesia: approx. 30 minutes,
  Soft-tissue anaesthesia: 60 - 120 minutes

Ubistesin 1:200,000
For routine procedures

Properties
- 4 % articaine and epinephrine (adrenaline) 1/200 000 as a vasoconstrictor
- Indications: Infiltration and nerve-block anaesthesia for routine-type interventions
- Only sulfite as a stabilizer
- Appropriate for adults and children aged 4 and over
- Average duration of action:
  Pulpal anaesthesia: approx. 45 minutes,
  Soft-tissue anaesthesia: 120 - 240 minutes

Ubistesin 1:100,000
For complicated procedures requiring prolonged anaesthesia

Properties
- 4 % articaine and epinephrine (adrenaline) 1/100 000 as a vasoconstrictor
- Indications: Infiltration and nerve-block anaesthesia for complex interventions requiring prolonged anaesthesia
- Only sulfite as a stabilizer
- Appropriate for adults and children aged 4 and over
- Average duration of action:
  Pulpal anaesthesia: approx. 75 minutes,
  Soft-tissue anaesthesia: > 240 minutes

Mepivastesin 30 MG/ML
For minor procedures in specific patient groups

Properties
- 3 % mepivacaine
- Indications: Infiltration and nerve-block anaesthesia for simple routine procedures
- Without epinephrine (adrenaline) and stabilizer
- Appropriate for adults and children aged 4 and over
- Average duration of action:
  Pulpal anaesthesia: approx. 20 – 40 minutes,
  Soft-tissue anaesthesia: 45 – 90 minutes

Pluraject™ 2 Aspiration Syringe
For cylindrical glass cartridges with perforated stoppers

Properties
- Compact and lightweight for better handling
- Cartridges are easy to insert and remove thanks to the flip mechanism
- Appropriate for both active and passive aspiration
- Inch and metric thread available

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.

5 IMPORTANT QUALITY QUESTIONS

1 Which measurements are implemented to assure high quality? Pierrel has implemented:

- a number of in-process controls during manufacturing
- a 100% opto-electronic control before labelling
- high quality standards according to GMP*, GLP*, and GDP*
- a Qualified Person responsible for the manufacturing and control process

2 Does Pierrel siliconizes the cartridges?:

Yes, for sure:

- to get a homogenous silicon monolayer at the inner side of the cartridge
- to protect adrenaline from degradation – no metal ions release from the glass
- to get an excellent gliding performance of the rubber stopper

3 Is the product latex-free?

Yes! Pierrel does not use:

- rubber stopper and discs made from latex
- latex in any equipment in the entire manufacturing process
- latex may cause allergy like reddening of skin, urticaria, pruritus up to an anaphylactic shock.

4 Does the solution contain preservatives?*

Pierrel does not use:

- any preservative like methyl parabene Pierrel does use:
- sulfite as an antioxidant in a low concentration;
- sulfite as an important ingredient to protect the vasoconstrictor from degradation

5 Does the product contain EDTA?*

Absolutely not.

- EDTA (edetate disodium, a chelating agent) is not used in the formulation of Pierrel dental anesthetics

* GMP: Good Manufacturing Practice
* GLP: Good Laboratory Practice
* GDP: Good Distribution Practice
* Preservatives may cause allergy like reddening of skin, urticaria, pruritus up to an anaphylactic shock
* EDTA may cause nausea, vomitus and headache

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; Ubistesin™ 1/400 000, 40 mg/ml + 2.5 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); Ubistesin 1/400 000, 1 ml solution for injection contains: Active substances Articaine hydrochloride 40 mg, Epinephrine (Adrenaline) 2.5 micrograms (as hydrochloride); Excipients Sodium sulphite (E221) 0.6 mg, Sodium chloride, Water for injections, Hydrochloric acid 14 % and Sodium hydroxide solution, 9 % for adjusting the pH-value

CLINICAL PARTICULARS
Therapeutic indications: 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. Ubistesin 1/400 000 is a solution for injection exclusively used in dentistry for infiltration and nerve-block anaesthesia during routine procedures with a duration up to 30 min, such as uncomplicated extractions and cavity and crown stump preparations. Ubistesin is indicated in adults, adolescents and children aged 4 years (ca. 20 kg body weight) and older.

Contraindications: Ubistesin must not be used in children under 4 years of age (<20 kg body weight); in case of hypersensitivity to the active substances, sodium sulphite (E221) or to any of the excipients. Due to the active substance articaine, Ubistesin must not be used in the event of known allergy or hypersensitivity to local anaesthetics of the amide type; known 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. 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 must no 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).
POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them. Serious side effects Severe Allergic Reactions (Frequency not known): If you notice one of the following symptoms within a day of the dental procedure, tell your dentist immediately as they may be signs of an allergy and might in very rare cases evolve into a serious reaction (anaphylactic shock): Swelling of your face, lips, tongue or throat; Itching, rash, inflammation of skin or mucosa. Hypersensitivity testing is strongly recommended to avoid such events in the future. Sodium sulphite (E221): May rarely cause severe hypersensitivity reactions and bronchospasm. Nerve Disturbances (may affect up to 1 in 100 people): If you feel numbness, tingling, stinging, taste problems or eye disorders within one day of the dental procedure please contact your dentist. In general these nerve disturbances are only transient. In very rare cases they persist for longer time, but disappear within a few months. Other side effects Common (may affect up to 1 in 10 people): Headache, pain, tenderness, swelling.
Uncommon (may affect up to 1 in 100 people): Restlessness, dizziness, ear pain, feeling sick, vomiting, inflammation of gingiva, excessive sweating, bruise, low or high blood pressure, increased heart rate. Rare (may affect up to 1 in 1000 people): Sleepiness, fainting, pallor, weakness, fatigue, malaise, chills, strong or fast heartbeat, twitching of the eyelid, inflammation of lips, mucosa, mouth, nasal congestion, too much or too little salivary secretion, thirst, diarrhoea, obstipation, abdominal pain, mouth injury, nerve injury, bleeding. Frequency not known: Anxiety, abnormal heart rate, cardiovascular disorder, breathing difficulties, consciousness disturbance, convulsion, fever, tinnitus. Additional side effects in children and adolescents Neither data from clinical studies nor postmarketing observations revealed differences in safety between adults, children and adolescents.
PRESCRIPTION: Information shortened. For further details please refer to the instructions for use.

MEPIVASTESIN™, 30 mg/ml, solution for injection.
CLINICAL PARTICULARS, Therapeutic indications Local anaesthesia (infiltration and conduction anaesthesia) in dentistry. MEPIVASTESIN is used for simple extractions as well as for cavity and stump preparations. MEPIVASTESIN is particularly suitable for patients, in whom a vasoconstrictive adjunct is contraindicated.

MEPIVASTESIN is used in adults, adolescents and children over 4 years of age (approximately 20 kg body weight). Contraindications MEPIVASTESIN must not be used in children under 4 years of age (approximately 20 kg body weight); cases of hypersensitivity to the active substance or to any of the excipients. Due to the active substance mepivacaine (a local anaesthetic), MEPIVASTESIN must not be used in the following cases known: allergy or hypersensitivity to amide-type local anaesthetics; severe, uncontrolled or untreated cardiac impulse formation or conduction system disturbances (e.g. II and III degree AV block, marked bradycardia); acute congestive heart failure; severe hypotension.
POSSIBLE SIDE EFFECTS Like all medicines, this medicine can cause side effects, although not everybody gets them. Serious side effects Severe allergic reactions (frequency not known): Please tell your dentist immediately if you notice any of the following symptoms within one day after your dental treatment, as these may be a sign of an allergy and may trigger a severe reaction: Swelling of the face, lips, tongue or throat; Itching, rash, inflamed skin or mucous membranes; Hypersensitivity: it is strongly recommended that tests be carried out, in order to avoid such events in the future. Nerve disorders (frequency not known) If you experience numbness, tingling, stinging, problems in taste or impaired vision within one day after your dental treatment, please tell your dentist. Nerve disorders can persist for prolonged periods, but in most cases wear off within a few months. Other side effects Common (up to 1 in 10 patients treated): Treatment-induced pain (insufficient effect). Uncommon (up to 1 in 100 patients treated): Dizziness, fainting; nausea; excessive sweating; swelling or blisters at the injection site; bruising. Rare (up to 1 in 1,000 patients treated): Strong or rapid heartbeat; difficulty swallowing; excessive salivation; irritation or pain at the injection site. Frequency not known: Light-headedness, unconsciousness; impaired sense of smell; insomnia; cardiovascular impairment; low or high blood pressure, circulatory collapse, drop in pulse; pallor; vomiting; chills. Additional side effects in children and adolescents Data from clinical studies or postmarketing surveillance have shown no differences regarding safety between adults, children and adolescents.
PRESCRIPTION: Information shortened. For further details please refer to the instructions for use.

DATE OF REVISION OF THE TEXT UBISTESIN AND MEPIVASTESIN: August 2024.
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Please see or download the full prescribing information.

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PIERREL

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BROCHURE FOR DENTAL PROFESSIONALS
Ver 01/2025