

Package leaflet: Information for the user

Ultracain® 1%-Suprarenin® 50 ml

10 mg/ml / 0.006 mg/ml solution for injection

Articaine hydrochloride / epinephrine hydrochloride

Read all of this leaflet carefully before your doctor gives this medicine to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ultracain 1%-Suprarenin¹ is and what it is used for
2. What you need to know before you are given Ultracain 1%-Suprarenin
3. How to use Ultracain 1%-Suprarenin
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1. What Ultracain 1%-Suprarenin is and what it is used for

Ultracain 1%-Suprarenin is a medicine for local numbness (local anaesthetic of the amide type). The solutions of Ultracain 1%-Suprarenin contain 0.5 mg/100 ml (1:200 000) epinephrine (adrenaline) as a vasoconstrictor to narrow blood vessels. Ultracain 1%-Suprarenin is used for local and regional nerve blocks.

2. What you need to know before you are given Ultracain 1%-Suprarenin

Ultracain 1%-Suprarenin must not be used

- if you are allergic to articaine or other amide type local anaesthetics,
- if you are allergic to epinephrine (adrenaline), sodium metabisulphite (Ph. Eur.), methyl-4-hydroxybenzoate (Ph. Eur.) or any of the other ingredients of this medicine listed in section 6,
- if you have a severe heart rhythm disorder (e.g. second and third degree AV block),
- if you have a very slow heartbeat,
- if you have acute heart failure (acute heart failure, e.g. after a heart attack),
- if you have very low blood pressure (shock),
- if you have bronchial asthma and hypersensitivity to sulphites (asthma attacks that are triggered by sulphites),
- if you have epilepsy that is not adequately controlled by appropriate medicinal treatment.

Due to the effects of the epinephrine (adrenaline) component, Ultracain 1%-Suprarenin must not be used

- for local anaesthesia of the bones at the ends of the arms and legs (e.g. fingers and toes) because there is a risk here of blocking the blood flow,
- if you have increased intraocular pressure (glaucoma, increased pressure inside the eye),
- if you have hyperthyroidism (increased thyroid function),
- if you have episodic acceleration of the heart rate (paroxysmal tachycardia),

¹Ultracain 1%-Suprarenin stands for Ultracain 1%-Suprarenin 50 ml.

- if you have a particular type of heart rhythm disorder (absolute arrhythmia with fast, irregular heartbeat),
- if you have had a heart attack in the last 3 to 6 months,
- if you have had a coronary artery bypass in the last 3 months,
- if you take certain beta blockers (e.g. propranolol); there is a risk of a hypertensive crisis (very high blood pressure) or a severe slowing of the heart rate,
- if you have a pheochromocytoma (tumour that produces adrenaline and which is usually located in the adrenal glands),
- if you have very high blood pressure,
- if you are also being treated with certain medicines for depression and Parkinson's disease (tricyclic antidepressants or monoamine oxidase (MAO) inhibitors) because these active substances may increase the cardiovascular effects of the epinephrine (adrenaline); this may be the case up to 14 days after ending treatment with MAO inhibitors.

Ultracain 1%-Suprarenin must not be given intravenously (into a vein).

For use in the eye or for anaesthesia near the spinal cord, Ultracain-Suprarenin may only be used from ampoules (Ultracain 1%-Suprarenin 5 ml or Ultracain 2%-Suprarenin 5 ml) because of the preservative in the vials.

Warnings and precautions

Please talk to your doctor or pharmacist before you are given Ultracain 1%-Suprarenin if you have one of the following diseases or one of the points applies to you:

- if you have a deficiency of a specific enzyme (cholinesterase deficiency) because the effect of Ultracain 1%-Suprarenin may last longer, and in some cases be more intense.
- if there is a local inflammation at the injection site. In this case, the uptake of Ultracain 1%-Suprarenin may be greater, which will reduce the effectiveness.

Ultracain 1%-Suprarenin may only be given after a careful medical examination

- if you have a blood coagulation disorder,
- if you are being treated with blood thinning medicines,
- if you have severe kidney or liver function disorders (e.g. because of a kidney infection or cirrhosis of the liver),
- if you are also being treated with halogenated inhaled anaesthetics (see “Using Ultracain 1%-Suprarenin together with other medicines”),
- if you have epilepsy (see section 4),
- if you have a disease called myasthenia gravis that causes muscle weakness,
- if you have a disease called porphyria that causes either neurological complications or skin problems,
- if you have low levels of oxygen in your body's tissues (hypoxia), high levels of potassium in the blood (hyperkalemia) or metabolic disorders caused by too much acid in the blood (metabolic acidosis).

If you also have one of the following diseases, Ultracain 1%-Suprarenin may only be used after a careful medical examination:

- cardiovascular diseases such as
 - heart failure (weakness of the heart muscles),
 - coronary heart disease (narrowing of the coronary blood vessels),
 - angina pectoris (reduced blood flow to the heart with tightness and chest pain),
 - after a heart attack,
 - heart rhythm disorders (irregular heartbeat),
 - high blood pressure,
 - atherosclerosis (narrowing of the arteries caused by deposits, e.g. of blood lipids),
 - cerebrovascular disease (disorders of the blood flow in the brain),

- after a stroke,
- chronic bronchitis, lung emphysema (pathological overinflation of the lungs),
- diabetes mellitus,
- severe anxiety disorders.

For patients who are being treated with blood thinners (e.g. heparin or acetylsalicylic acid), the tendency to bleed is increased overall. Unintentional puncture of a blood vessel during local anaesthesia can therefore lead to serious bleeding.

To avoid side effects, your doctor will

- insert an intravenous access for an infusion in at-risk patients and when using higher dosages (more than 25% of the maximum individual dose),
- choose a dosage that is as low as possible,
- carefully check before the injection that no blood vessels have been punctured,
- regularly check your vital parameters (checks of your heart, circulation and consciousness).

Ultracain 1%-Suprarenin is not compatible with alkaline reacting solutions.

Other medicines and Ultracain 1%-Suprarenin

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

It is particularly important to tell your doctor if you take/use one of the following medicines:

- sedatives (such as benzodiazepine, opioids),
- COMT inhibitors to treat Parkinson's disease (such as entacapone or tolcapone),
- medicines to treat psychoses such as neuroleptics.
- medicines to treat migraines and cluster headaches (such as methysergide or ergotamine),
- sympathomimetic vasopressors (such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline) that increase the blood pressure: If used within the last 24 hours, the planned dental/surgical treatment must be postponed,
- medicines to treat the heart and blood pressure (e.g. guanadrel, guanethidine, propranolol, nadolol). If you are being given other local anaesthetics at the same time, their effects on the cardiovascular system and nervous system may be increased and it can lead to additional side effects (toxicity) with Ultracain 1%-Suprarenin.

Ultracain 1%-Suprarenin contains the active substance epinephrine (adrenaline). This active substance narrows the blood vessels and increases the blood pressure. This vasopressor effect of epinephrine can be increased by certain medicines to treat depression and Parkinson's disease. Tricyclic antidepressants and MAO inhibitors therefore must not be taken at the same time (note section 2: "What you need to know before you are given Ultracain 1%-Suprarenin").

If you take certain beta blockers (e.g. propranolol), you must not be given Ultracain 1%-Suprarenin (see section "Ultracain 1%-Suprarenin must not be used").

Epinephrine (adrenaline) can inhibit the release of insulin from the pancreas, which may reduce the effect of oral antidiabetic drugs (medicines used to treat diabetes).

Using Ultracain 1%-Suprarenin at the same time as certain inhaled anaesthetics (e.g. desflurane, isoflurane or sevoflurane) may trigger heart rhythm disorders.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding or if you think that you may be pregnant or are planning to become pregnant, ask your dentist or pharmacist for advice before you are given this medicine.

If you are pregnant, your doctor should only use Ultracain 1%-Suprarenin after carefully weighing up the benefits and risks.

There is no information available about the use of articaine during pregnancy except at the time of the birth. Animal studies have shown that epinephrine (adrenaline) in higher doses than those used in medical anaesthesia has harmful effects on offspring. After unintentional injection of Ultracain 1%-Suprarenin into a blood vessel of the mother, the blood flow in the uterus may be reduced by the epinephrine (adrenaline) component. For anaesthesia during childbirth, there are no known negative effects of articaine on the newborn.

The active substances of Ultracain 1%-Suprarenin are rapidly broken down in the body. This means that the amounts of the active substances occurring in the breast milk are not harmful for the infant. With short-term use of Ultracain 1%-Suprarenin, you therefore do not have to stop breastfeeding.

Driving and using machines

After a procedure, your doctor will decide when you may again drive a vehicle or use machines. Relevant studies have shown that local anaesthesia with articaine does not have any noticeable effects on the normal ability to drive a vehicle.

Ultracain 1%-Suprarenin contains sodium.

This medicine contains less than 1 mmol (23 mg) sodium per ml, that is, it is almost “sodium free”.

3. How to use Ultracain 1%-Suprarenin

Ultracain 1%-Suprarenin is usually given by a doctor. Ask your doctor if you are unsure about how the medicine is given.

Ultracain 1%-Suprarenin should only be administered by people with appropriate knowledge of how to successfully perform the anaesthesia procedure.

Dose

In principle, only the smallest dose should be given to achieve the required, adequate anaesthesia. The dose must be determined for each individual based on the specific situation.

For children and older patients, the dose must be adjusted.

Unless otherwise prescribed by the doctor, the recommended dose (for adults with an average body size):

Recommended maximum doses: 5–6 mg/kg body weight, total 600 mg

Brachial plexus block	10–30 ml
Infiltration anaesthesia	10–40 ml

Route of administration

Solution for injection for specific local use.

If you have been given too much Ultracain 1%-Suprarenin

It is unlikely that you will be injected with too much of this medicine but if you start to feel unwell, tell your doctor. You may have the following symptoms with an overdose: e.g. agitation or restlessness, anxiety, confusion, disorientation, loss of balance, reddening of the face, nausea, vomiting, headache, involuntary trembling or quivering, convulsions, (epileptic) seizures, dizziness, dilated pupils, blurred vision, difficulty focusing the eyes, hearing disorders, inability to speak, severe weakness, stupor, drowsiness, loss of consciousness, muscle weakness, pale skin, coma, yawning,

abnormally slow or fast breathing, breathing problems and paralysis of breathing that can lead to death.

You may also develop disorders of the heart and circulatory system such as a drop or increase in blood pressure and heart rhythm disorders that can lead to loss of heart function.

Such disorders need to be monitored by your doctor and may need appropriate treatment by your doctor.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common (may affect up to 1 in 10 people)

- Nausea,
- Vomiting,
- Loss of sense of touch (hypoesthesia);
- Headaches that may be attributed to the epinephrine (adrenaline) component.

Uncommon (may affect up to 1 in 100 people)

- Racing heart (tachycardia), dizziness.

Not known (frequency cannot be estimated from the available data)

- Heart rhythm disorders, increase in blood pressure, decrease in blood pressure, slowed heartbeat (bradycardia), heart failure and shock (under some conditions, life threatening),
- Dose-dependent (particularly with a dose that is too high or unintentional injection into a blood vessel) disorders of the central nervous system, e.g.
 - restlessness, nervousness,
 - inability to move, drowsiness to loss of consciousness, coma,
 - breathing problems to breathing stopping,
 - muscle tremors, muscle convulsions to seizures,
- During or shortly after the injection of the local anaesthetic in the head region, impaired vision may develop (blurred vision, double vision, dilated pupils, blindness). This is usually temporary.
- Abnormal sensations (paresthesia), persistent loss of sense of touch and taste,
- Hypersensitivity reactions (allergic or allergy-like reactions) may occur. These may appear as swelling and/or inflammation at the site of injection. Hypersensitivity reactions that are not limited to the site of injection appear as
 - reddening,
 - itching,
 - red and watery eyes,
 - runny nose,
 - swelling of the face (angioedema) with swelling of the upper and/or lower lip and/or cheeks,
 - swelling around the larynx with a feeling of tightness and difficulty swallowing,
 - hives,
 - difficulty breathing up to anaphylactic shock.
- When used for pain relief during childbirth, particularly for paracervical blocks (PCB), the baby's heart rate may slow down (bradycardia). It is necessary to carefully monitor the baby's heart sounds.

- Sodium metabisulphite (Ph. Eur.) can in rare cases cause severe hypersensitivity reactions and spasms of the airways (bronchospasms). Hypersensitivity reactions may appear as vomiting, diarrhoea, wheezing, acute asthma attack, impaired consciousness or shock.
- Methyl-4-hydroxybenzoate can cause hypersensitivity reactions, also with delayed onset, and rarely spasms of the airways (bronchospasm).
- Peeling of the gums and development of ulcers,
- Peeling at the site of injection,
- Pain in the neck,
- Worsening of neuromuscular symptoms (such as skeletal muscle weakness, loss of hearing, inability to coordinate voluntary movements, impaired ability to think) in Kearns-Sayre syndrome,
- Nervousness, feelings of anxiety,
- Extremely good mood (euphoria),
- Wheezing (bronchospasm), asthma,
- Difficulty breathing,
- Ringing in your ears, extremely sensitive hearing,
- Swelling of the tongue, lips, gums and cheeks.
- Diarrhoea,
- Inflammation of the tongue and mouth,
- Difficulty swallowing,
- Burning mouth,
- Lockjaw (contraction of the jaw muscles that keep the mouth closed).

Special information

If you suddenly get a side effect or a side effect becomes worse, immediately tell a doctor. This is particularly important because some of these side effects (e.g. drop in blood pressure or breathing disorders) can be life threatening.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the

Bundesinstitut für Arzneimittel und Medizinprodukte
Pharmacovigilance Department
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn, Germany
Website: www.bfarm.de

By reporting side effects, you can help provide more information about the safety of this medicine.

5. How to store Ultracain 1%-Suprarenin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after “Use by” on the outer carton and the vial. The expiry date refers to the last day of the month indicated.

Do not store above 30°C. Store the vials in the outer carton to protect the contents from light.

The solution must be clear and colourless. If the solution has become coloured or cloudy, do not use the medicine.

Note about shelf life after opening or preparation

Opened vials should be used up within 2 days. The time of the first opening must be noted on the label.

Do not throw this medicine away via waste water (e.g. by pouring into the toilet or washbasin). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. You can find more information at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and other information

What Ultracain 1%-Suprarenin contains

The active substances are articaine hydrochloride and epinephrine hydrochloride.

1 ml solution for injection contains 10 mg articaine hydrochloride and 0.006 mg epinephrine hydrochloride.

The other ingredients are:

Methyl-4-hydroxybenzoate (Ph. Eur.) (paraben, E-218) 1 mg/ml, sodium metabisulphite (Ph. Eur.), sodium chloride, hydrochloric acid 10% (for pH adjustment), water for injection.

What Ultracain 1%-Suprarenin looks like and contents of the pack

Ultracain 1%-Suprarenin is a clear, colourless solution and is available in packs of 5 vials, each containing 50 ml solution for injection. There is also a hospital pack available with 100 vials each containing 50 ml solution for injection.

Not all pack sizes may be marketed.

Marketing authorisation holder

Septodont GmbH
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D-53859 Niederkassel, Germany

Manufacturer

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94100 Saint-Maur-des-Fossés
France

This package leaflet was last revised in September 2025.

Ultracain 1%-Suprarenin 5 ml as well as Ultracain 2%-Suprarenin 5 ml and Ultracain 2%-Suprarenin 50 ml are also available.

Ultracain is also available without the addition of Suprarenin.