

UBISTESIN 1:200,000 and UBISTESIN FORTE 1:100,000

Articaine hydrochloride and adrenaline (epinephrine) hydrochloride

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you use UBISTESIN or UBISTESIN FORTE.

This leaflet answers some common questions about UBISTESIN or UBISTESIN FORTE. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking UBISTESIN or UBISTESIN FORTE against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT IS UBISTESIN and UBISTESIN FORTE USED FOR

UBISTESIN and UBISTESIN FORTE contain the active ingredients: Articaine hydrochloride, a local anaesthetic to prevent the pain, and adrenaline (epinephrine) hydrochloride, a vasoconstrictor, which makes it last longer (adrenaline (epinephrine) narrows the blood vessels at the site of injection, which keeps the anaesthetic where it's needed for a longer time) and controls bleeding during the surgery.

UBISTESIN and UBISTESIN FORTE belong to a group of medicines called local anaesthetics. UBISTESIN or UBISTESIN FORTE is injected into the mouth where it makes the nerves unable to pass messages to the brain.

Your dentist will have explained why you are being given UBISTESIN or UBISTESIN FORTE.

Follow all directions given to you by your dentist carefully. They may differ from the information contained in this leaflet. Ask your dentist if you want more information.

UBISTESIN and UBISTESIN FORTE are not addictive.

BEFORE YOU ARE GIVEN UBISTESIN OR UBISTESIN FORTE

When you must not be given UBISTESIN or UBISTESIN FORTE

- You are allergic to adrenaline (epinephrine), articaine, or any local anaesthetic and any other ingredient included in the product.
- You are asthmatic or have broncho-spasmodic (difficulty in breathing) reactions to sulfites.
- You lack a natural chemical substance called cholinesterase in your blood (plasma cholinesterase deficiency)
- You have an overactive thyroid gland, whether or not treated for this.
- You have a tumour called pheochromocytoma (adrenal gland)

- You suffer from severe heartbeat coordination problems (cardiac disorders, atrioventricular block)
- **Children under the age of 4 years old.**

Before you are given UBISTESIN OR UBISTESIN FORTE:

You must tell your dentist if you have allergies to:

- **other local anaesthetics**
- **any other medicines**
- **any other substances such as foods, preservatives or dye**
- **any other ingredients listed at the end of this leaflet**

Tell your dentist if:

- You have problems with your heart, blood vessels and heart rhythm.
- You have epilepsy.
- You have hepatic (liver) or renal (kidney) diseases.
- You suffer from a disease called Myasthenia Gravis causing weakness in the muscles
- You suffer from a condition called Porphyria which causes either neurological complications or skin problems
- You have diabetes
- You have cerebrovascular insufficiency (obstruction of one or more arteries that supply blood to the brain)
- You suffer from a disease called angle-closure glaucoma which affects your eyes
- You have inflammation or infection in the area to be injected
- You are more than 70 years old
- **You are pregnant or breast-feeding.** If UBISTESIN OR UBISTESIN FORTE is used when you are breast-feeding you should not breast-feed for at least 4 hours following use of UBISTESIN OR UBISTESIN FORTE.
- You have any other medical conditions.

Taking other medicines

Tell your dentist if you are taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your dentist should take special attention if you are taking the following medicines:

- Other local anaesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane)
- Sedatives (such as benzodiazepines, opioids)
- Mono Amine Oxidase Inhibitors (MAOI) or tricyclic antidepressants (medicines used to treat depression), or have taken this type of medicine within the last two weeks.
- COMT-inhibitors to treat Parkinson's disease (such as entacapone) medicines used to treat irregular heartbeats (eg digitalis, quinidine)
- Phenothiazines (medicines used to treat mental illnesses).

- Cimetidine (medicine used to treat reflux and stomach or duodenal ulcers)
- Thyroid hormone
- Heart and blood pressure medicines
- Medicine used to treat migraines (eg ergotamine or methysergide)
- Medications to thin the blood and prevent blood clotting (eg antiplatelets, anticoagulants)
- Sympathomimetic vasopressors* (eg oxymetazoline used to treat swelling or inflammation of the nose)

***If a sympathomimetic vasopressor such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline has been used within the past 24 hours, the planned dental treatment must be postponed.**

These medicines may be affected by UBISTESIN or UBISTESIN FORTE or may affect how well it works. Your dentist may need to adjust your dose.

HOW UBISTESIN AND UBISTESIN FORTE IS GIVEN?

UBISTESIN and UBISTESIN FORTE are given by injection to cause loss of feeling before and during dental procedures.

Your dentist will explain to you why you are being treated with UBISTESIN or UBISTESIN FORTE and what dose you will be administered.

Your dentist will inject UBISTESIN or UBISTESIN FORTE into your oral (mouth) cavity. This will result in an area of numbness at the site of the injection.

One cartridge is usually sufficient but your dentist may give you a greater quantity. He will adjust the dosage according to your age, your health, your weight and the dental work to be performed. If only a portion of a cartridge is used the remainder must be discarded.

Overdose

Your dentist will determine the amount of solution, which is needed to provide pain control during your treatment, and it is very unlikely that you would receive too much

However, some persons tolerate articaine and adrenaline (epinephrine) less well than others and the signs and symptoms of too much of these substances in your blood include: nervousness, dizziness, blurred vision, nausea, trembling, convulsions, slow or irregular heartbeat, troubled breathing.

Tell your dentist immediately if you experience any of these symptoms during or shortly after your treatment.

WHILE YOU ARE USING UBISTESIN OR UBISTESIN FORTE

Things you must not do:

Do not eat or drink anything until the feeling has returned to your mouth.

You may burn or bite yourself.

Things to be careful of:

- Be careful driving or operating machinery until you know how it affects you. You may be drowsy and your reflexes may be slow. This medicine

may cause dizziness, light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

- Do not drink alcohol immediately before or after you are given it.
- If you drink alcohol while you are being given it, your blood pressure may drop making you feel dizzy and faint.
- Please talk to your dentist or pharmacist about these possibilities if you think they may bother you.

SIDE EFFECTS

Tell your dentist as soon as possible if you do not feel well when using UBISTESIN or UBISTESIN FORTE.

All medicines may cause side effects in some patients. Although not all of these side effects may occur, if they do occur they may need medical attention. While you are in your dentist's office, your dentist will carefully follow the effects of UBISTESIN or UBISTESIN FORTE. However, some effects may not be noticed or appear later.

Tell your dentist if you notice any of the following serious side effects:

- Swollen face, tongue or pharynx, difficulty swallowing or breathing, hives
- Rash, itching, swelling of the throat and difficulty breathing (this could be symptoms of an allergic reaction)
- Horner's syndrome – a combination of drooping of the eyelid and constriction of the pupil

These serious side effects occur rarely (may affect up to 1 in 1,000 people).

Common side effects: may affect up to 1 in 10 people

- you have a headache
- your heart is beating slowly, rapidly or irregularly
- your blood pressure is low
- you are feeling dizzy, faint, look pale
- you have facial swelling (tongue, lips, gums) or inflammation of gums, numbness of your tongue, mouth and/or lips
- you have numbness or reduced sense of touch in and around mouth
- your taste is disturbed or you have lost your taste function, metallic taste
- you have neuropathic pain (pain due to nerve damage)
- you have an increased sensitivity to heat

Uncommon side effects: may affect up to 1 in 100 people

- High blood pressure
- Burning sensation
- Inflammation of the tongue or mouth
- Nausea, vomiting, diarrhoea
- Rash, itching
- Pain in the neck or at the site of injection
- Pain

Rare side effects: may affect up to 1 in 10,000 people

- Wheezing, (bronchospasm), asthma, breathing difficulty
- Fatigue, weakness
- Anxiety, nervousness

- Drowsiness
- Facial nerve disorder (paralysis)
- Involuntary eye movement
- Muscle twitching, involuntary muscle contraction
- Convulsions or fits
- Double vision, temporary blindness
- Balance disorder, vertigo
- Loss of consciousness
- Buzzing in the ears, sensitivity to hearing

If you are experiencing any of these, you may have had a serious (allergic) reaction to UBISTESIN OR UBISTESIN FORTE. You may need urgent medical attention or hospitalisation.

Tell your dentist if you notice anything else that is making you feel unwell.

Some people may get other side effects while using UBISTESIN OR UBISTESIN FORTE.

You may be hypersensitive to sulfites and therefore show allergic symptoms to UBISTESIN or UBISTESIN FORTE such as breathing difficulties and/or skin reactions.

If you have problems with your blood vessels, circulation or have high blood pressure, you may react exaggeratedly to the vasoconstrictor contained in UBISTESIN OR UBISTESIN FORTE and develop a small injury at the site of injection.

AFTER USING UBISTESIN AND UBISTESIN FORTE

Storage

All medicines must be kept in a safe place out of the reach of children.

UBISTESIN and UBISTESIN FORTE will be stored by your dentist under recommended conditions.

The medicine should be stored below 25°C and protected from light.

PRODUCT DESCRIPTION

What it looks like

Solution is clear, not opalescent and colourless.

Active Ingredients

UBISTESIN contain Articaine hydrochloride 40 mg and Adrenaline (epinephrine) hydrochloride 0.006 mg

UBISTESIN FORTE contain Articaine hydrochloride 40 mg and Adrenaline (epinephrine) hydrochloride 0.012 mg

Other Ingredients

sodium sulphite, sodium chloride, hydrochloric acid, sodium hydroxide solution and water for injections

FURTHER INFORMATION

Only a dentist can administer this product. This leaflet provides only a summary of the information known about UBISTESIN and UBISTESIN FORTE. If you have any questions, want to know more about this medicine, or have some doubts, ask your dentist.

SPONSOR

3M Australia Pty Ltd
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REGISTRATION NUMBERS

UBISTESIN – AUST R 165573

UBISTESIN FORTE – AUST R 165574

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