

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Espeselin Forte

40 mg/ml + 10 microgram/ml

Solution for injection

Articaine hydrochloride/Adrenaline (epinephrine)

Read all of this leaflet carefully before you start using this medicine 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, dentist or pharmacist.
- If you get any side effects, talk to your doctor, dentist or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Espeselin Forte is and what it is used for
2. What you need to know before you use Espeselin Forte
3. How to use Espeselin Forte
4. Possible side effects
5. How to store Espeselin Forte
6. Contents of the pack and other information

1. What Espeselin Forte is and what it is used for

Espeselin Forte is used to numb (anaesthetise) your oral cavity during dental procedures. This medicine contains two active substances:

- articaine, a local anaesthetic which prevents pain, and
- adrenaline (epinephrine), a vasoconstrictor which narrows the blood vessels at the site of injection, and thereby prolongs the effect of articaine. It also decreases bleeding during surgery.

You will be given Espeselin Forte by a dentist.

Espeselin Forte is for children over 4 years of age (ca. 20 kg in body weight), adolescents and adults.

Espeselin Forte is more adapted to procedures lasting longer or with possible significant bleeding.

2. What you need to know before you are given Espeselin Forte

Do not use Espeselin Forte if you suffer from any of the following conditions:

- allergy to articaine or epinephrine or any of the other ingredients of these medicines (listed in section 6);
- allergy to other local anaesthetics;
- epilepsy, not adequately controlled by drug treatment.

Warnings and precautions

Talk to your dentist before using Espesolin Forte if you suffer from any of the following conditions:

- severe heart rhythm disorders (e.g. second and third-degree AV block);
- acute heart failure (acute heart weakness, e.g. unexpected chest pain while resting or after myocardial infarction (e.g. heart attack));
- low blood pressure;
- abnormal rapid heartbeats;
- heart attack in the last 3 to 6 months;
- coronary artery bypass surgery in the last 3 months;
- taking some medicines for blood pressure called beta blockers, such as propranolol. There is the danger of a hypertensive crisis (very high blood pressure) or severe slowing of the pulse (see section other medicines);
- very high blood pressure;
- simultaneously taking some medicines for the treatment of depression and Parkinson's disease (tricyclic antidepressants). These medicines may intensify the effects of epinephrine.
- epilepsy;
- lacking of a natural chemical substance called cholinesterase in your blood (plasma cholinesterase deficiency);
- problems with your kidneys;
- serious problems with your liver
- a disease called *Myasthenia Gravis* causing weakness in the muscles;
- *Porphyria* which causes either neurological complications or skin problems;
- use other local anaesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane);
- taking medications called antiplatelets or anticoagulants, to prevent narrowing or hardening of your blood vessels in the arms and legs;
- are more than 70 years old.
- have or have had any heart problem
- have uncontrolled diabetes;
- severely overfunctioning thyroid (thyrotoxicosis);
- tumour called pheochromocytoma;
- a disease called angle-closure glaucoma which affects your eyes;
- inflammation or infection in the area to be injected.
- decreased amounts of oxygen in the body's tissues (hypoxia), high blood potassium (hyperkalaemia) and metabolic disorders as a result of too much acid in the blood (metabolic acidosis).

Other medicines and Espesolin Forte

Tell your dentist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your dentist if you are taking any of the following medicines:

- other local anaesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane);
- sedatives (such as benzodiazepine, opioids), for example to reduce your apprehension before the dental procedure;
- heart and blood pressure medicines (such as guanadrel, guanethidine, propranolol, nadolol,)
- tricyclic antidepressants used to treat depression (such as amitriptyline, desipramine, imipramine, nortriptyline, maprotiline and protriptyline);
- COMT-inhibitors to treat Parkinson's disease (such as entacapone or tolcapone);
- MAO inhibitors used to treat depressive or anxiety disorders (such as moclobemide, phenelzine, tranylcypromine, linezolid);
- medicines used to treat irregular heartbeats (for example digitalis, quinidine);
- medicines used for migraine attacks (such as methysergide or ergotamine);
- sympathomimetic vasopressors (such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline), used to raise the blood pressure: if used within the past 24

- hours, the planned dental treatment has to be postponed.
- neuroleptic drugs (for example phenothiazines).

Espeselin Forte with food

Avoid eating, included chewing-gum, until normal sensation is restored because there is a risk that you may bite your lips, cheeks or tongue, especially in children.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist or doctor for advice before using this medicine.

Your dentist or doctor will decide if you can use Espeselin Forte during pregnancy. Breast-feeding can be resumed after 5 hours following anaesthesia.

No adverse effects on fertility are anticipated at doses used for a dental procedure.

Driving and using machines

If you experience side effects, including dizziness, blurred vision or fatigue, you should not drive or operate machinery until you recover your abilities (generally within 30 minutes following the dental procedure).

Espeselin Forte contains sodium sulfite and sodium.

- This medicine contains sodium sulfite (E 221), that may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains less than 1 mmol sodium (23 mg) per cartridge, that is to say essentially "sodium free".

If there is any risk of an allergic reaction, your dentist will choose a different medicine for anaesthesia.

3. How to use Espeselin Forte

Only physicians or dentists are trained to use Espeselin Forte.

Your dentist will choose Espeselin Forte and determine the appropriate dose taking into account your age, your weight, your general health and the dental procedure.

The lowest dose leading to effective anaesthesia should be used. This medicine is given by a slow injection in the oral cavity.

If you are given more Espeselin Forte than you should

It is not likely that you will be given too much of this injection but if you should begin to feel unwell, tell your dentist. Symptoms of overdose include severe weakness, paleness of the skin, headache, feeling agitated or restless, feeling disorientated, losing your balance, involuntary trembling or quivering, dilation of the pupil, blurred vision, problems clearly focusing an object, speech disorders, dizziness, convulsions, stupor, loss of consciousness, coma, yawning, abnormally slow or rapid breathing which could lead to temporarily stopping breathing, failure of the heart to contract effectively (called cardiac arrest).

If you have any further questions on the use of this medicine, ask your dentist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. While you are in your dentist's office, your dentist will carefully follow the effects of Espesolin Forte.

Inform your dentist, doctor or pharmacist immediately if you experience one of the following serious side effects:

- swollen face, tongue or pharynx, difficulty to swallow, hives or difficulties to breath (angioedema)
- rash, itching, swelling of the throat and difficulty breathing: this might be symptoms of an allergic (hypersensitivity) reaction.
- a combination of drooping of the eyelid and constriction of the pupil (Horner's syndrome) These side effects happen rarely (may affect up to 1 in 1,000 people).

Other side effects not listed above may also occur in some patients.

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

- inflammation of the gums
- neuropathic pain – pain due to nerve damage
- numbness or reduced sense of touch in and around the mouth
- metallic taste, taste disturbance or loss of taste function
- increased, unpleasant or abnormal sense of touch
- increased sensitivity to heat
- headache
- abnormal rapid heartbeat
- abnormal slow heartbeat
- low blood pressure
- swelling of tongue, lips and gums

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

- burning sensation
- high blood pressure
- inflammation of the tongue and mouth
- nausea, vomiting, diarrhea
- rash, itching
- pain in the neck or reaction at the site of the injection

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

- nervousness (restlessness), anxiety
- facial nerve disorder (facial palsy)
- somnolence
- involuntary eye movement
- double vision, temporary blindness, reduced visual acuity
- drooping of the eyelid, and constriction of the pupil (Horner's syndrome)
- recession displacement of the eyeball into the orbit (*Enophthalmos*)
- dilated pupils (mydriasis)
- eye pain
- ringing of the ears, over-sensitivity of hearing
- palpitations
- hot flush
- pallor
- wheezing (bronchospasm), asthma
- difficulty breathing
- exfoliation and ulceration of the gums

- exfoliation of the injection site
- hives (urticarial)
- muscle twitch, involuntary muscle contraction
- fatigue, weakness
- chills

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

- transient or persistent loss of sensitivity, extended numbness and loss of taste

Not known: frequency cannot be estimated from the available data

- extremely good mood (euphoria)
- feeling faint/fainting
- seizures, including generalized
- heartbeat coordination problems (conduction disorders, atrioventricular block, heart arrest)
- increased amount of blood in a part of the body leading to congestion of blood vessels
- widening or narrowing of blood vessels
- hoarseness
- difficulty in swallowing
- swelling of cheeks and local swelling
- Burning mouth syndrome
- redness of the skin (erythema)
- abnormally increased sweating,
- worsening of the neuromuscular symptoms in Kearns-Sayre syndrome
- feeling hot or feeling cold
- lock-jaw

Reporting of side effects

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

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of these medicines.

5. How to store Espesolin Forte

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

Do not use this medicine after the expiry date which is stated on the label and outer package after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Keep the cartridges in the tightly closed original package in order to protect from light. Do not use this medicine if you notice that the solution is cloudy or discoloured.

Cartridges should be carefully taken out of the tin in order to avoid cutting injuries

The cartridges are intended for single use. Use immediately after the opening of the cartridge. Unused solution must be discarded.

Do not throw away any medicines via wastewater or household waste. Your dentist knows how to throw away medicines no longer used. These measures will help protect the environment.

6. Contents of the pack and other information

What Espestesin Forte contains

The active substances are articaine hydrochloride and epinephrine (adrenaline) (as hydrochloride).

- 1 ml of Espestesin Forte contains 40 mg of articaine hydrochloride and 10 micrograms of adrenaline (epinephrine) (as adrenaline hydrochloride).
- Each cartridge of 1.7-ml of solution for injection of Espestesin Forte contains 68 mg of articaine hydrochloride and 17 micrograms of adrenaline (epinephrine) (as adrenaline hydrochloride).
- The other ingredients are sodium sulfite (E221), sodium chloride, and water for injections as well as hydrochloric acid 14% and sodium hydroxide 9% for adjusting the pH-value.

What Espestesin Forte look like and contents of the pack

Espestesin Forte is a clear and colourless solution.

It is packed in single use glass cartridges sealed at the base by a mobile rubber plunger and at the top by a rubber seal kept in place by an aluminium cap.

Tin with 50 cartridges of 1.7 ml each

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Pierrel S.p.A.

Strada Statale Appia 7bis, 46/48

81043 Capua (CE)

Italy

Manufacturer

3M Healthcare Germany GmbH

Carl-Schurz-Strasse 1

DE-41453 Neuss

Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Ubistesin Adrenaline 1/100 000, 40 mg/ml + 10 microgram/ml, oplossing voor injectie

Finland: Ubistesin forte 40 mg/ml + 10 mikrog/ml, injektionseste, liuos

Germany: Ubistesin 1/100 000 40 mg/ml + 10 Mikrogramm/ml Injektionslösung

Ireland: Espestesin Forte 40 mg/ml + 10 microgram/ml solution for injection

Luxembourg: Ubistesin Adrenaline 1/100 000, 40 mg/ml + 10 microgram/ml, sol. inj.

Netherlands: Ubistesin 4% articaine met 1/100 000 adrenaline, oplossing voor injectie

This leaflet was last revised in

November 2023



The following information is intended for medical or healthcare professionals only:

As the product is exclusively used by dentist it is intended to add the complete SPC as tear off section at the end of the printed PIL.