PACKAGE LEAFLET

Package leaflet: Information for the user

Orabloc 1:100,000
Articaine hydrochloride and adrenaline (epinephrine) solution for injection 1:100,000

Read all of this leaflet carefully before this medicine is given to you by your dentist 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 dentist, doctor 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 Orabloc is and what it is used for

Orabloc is a medicine for local anaesthetisation (local anaesthetic) in dentistry.
It contains the active ingredients articaine (local anaesthetic) and adrenaline (epinephrine). Adrenaline (epinephrine) narrows the blood vessels. This reduces blood flow at the point at which you receive the needle from your doctor (local anaemia). This reduces bleeding in treatments and extends the effect of the local anaesthetisation.

Orabloc is used for the local anaesthetisation of dental treatments in adults, adolescents and children from 4 year old, including:

- surgery of the oral mucosa or bone in which a greater reduction in blood flow is important,
- surgery of the dental pulp,
- removal of broken teeth,
- longer surgical interventions,
- oral surgery of the bone with open gums,
- removal of cysts (fluid-filled cavities in the tissue),
- surgery in the gum area or at the gum-tooth margin,
- removal of root apices.

2. What you need to know before you are given Orabloc

Do not use Orabloc

- if you are allergic to articaine, or other local anaesthetic of the acid amide type, to adrenaline (epinephrine) or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from severe heart rhythm disorders (e.g. second and third-degree AV block),
- if you have a very low pulse,
- if you suffer from acute heart failure (acute heart weakness, e.g. after myocardial infarction (e.g. heart attack)),
- if you have very low blood pressure,
- if you are a bronchial asthmatic and suffer from sulphite hypersensitivity (asthma attacks, triggered by sulphite).

- in children under 4 years of age

Owing to the effects of the epinephrin (adrenaline) fraction, Orabloc must not be used on you:
- if local anaesthetisation in a 'terminal area' of the blood vessels is being carried out (i.e. in an area supplied with blood only by the branches of a single artery),
- if you have raised intraocular pressure (glaucoma),
- if you have an overactive thyroid,
- if you suffer from sudden-onset tachycardia (paroxysmal tachycardia),
- if you suffer from a particular form of heart rhythm disorders (absolute arrhythmia with high pulse rate),
- if you had a myocardial infarction (e.g. heart attack) in the last 3 to 6 months,
- if you had coronary artery bypass surgery in the last 3 months,
- if you take certain beta blockers, such as propranolol. There is the danger of a hypertensive crisis (very high blood pressure) or severe slowing of the pulse,
- if you suffer from phaeochromocytoma (adrenaline-producing tumour generally in the adrenal medulla),
- if you have very high blood pressure,
- if you are treated simultaneously with certain medicines for the treatment of depression and Parkinson's disease (tricyclic antidepressants, MAO inhibitors). These medicines may intensify the cardiovascular effects of adrenaline (epinephrine). This may apply up to 14 days after the conclusion of treatment with MAO inhibitors.

Orabloc must not be administered intravenously (into a vein).

Warnings and precautions

Talk to your dentist or pharmacist before Orabloc is used:

- if you have a deficiency of a specific enzyme (cholinesterase deficiency). This may lead to a slowed and possibly intensified action of Orabloc
- if there is local inflammation or infection at the site at which the syringe is to be inserted. Increased absorption of Orabloc takes place in this event, with efficacy being reduced.

Orabloc may be administered only after careful medical examination if you:

- suffer from disturbances of blood clotting,
- suffer from severe kidney or liver insufficiency (e.g. in the case of nephritis or cirrhosis of the liver),
- are receiving concomitant treatment with halogenated inhalation anaesthetics (see Using other medicines),
- suffer from epilepsy (see section 4).

If you suffer from any of the following diseases, Orabloc may be administered only after careful medical examination and your dentist should consider using Orabloc 1:200,000 Articaine hydrochloride 4% with adrenaline (epinephrine) solution for injection 1:200,000 instead of Orabloc 1:100,000 Articaine hydrochloride and adrenaline (epinephrine) solution for injection 1:100,000 as the former contains less adrenaline (epinephrine):
- cardiovascular diseases, e.g.:
  - angina pectoris (disturbance of blood flow to the heart with pain and feeling of tightness in the chest),
  – arteriosclerosis (narrowing of arteries by deposits, e.g. by blood fats),
  - heart failure (heart muscle weakness),
  - coronary heart disease (narrowing of the coronary vessels),
  - angina pectoris (disturbance of blood flow to the heart with pain and feeling of tightness in the chest),
  - after a myocardial infarction (eg heart attack),
  - heart rhythm disorders (irregular pulse),

  - high blood pressure,
  - disorders of blood flow to the brain,
  - after a stroke,
- chronic bronchitis, pulmonary emphysema (pathological overinflation of the lungs),
- diabetes (diabetes mellitus),
- severe anxiety states.

To avoid side effects, your dentist will
- check your medical history and concomitant treatments,
- practise a test injection if there is a risk of allergy to the product,
- choose the dosage as low as possible,
- before the injection, carefully check that he has not struck a blood vessel.

Use of the product can result in prolonged numbness in the area of the mouth after the dental procedure: in young children, care should be taken to avoid self-biting, which could result in soft tissue injury.

Other medicines and Orabloc

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

If you have simultaneously used other medicines for local anaesthetisation, their effects on the cardiovascular system and nervous system may be intensified.

Orabloc contains the active ingredient adrenaline (epinephrine). This active ingredient narrows the blood vessels and raises blood pressure. The blood pressure-raising effect of adrenaline (epinephrine) may be intensified by certain medicines for the treatment of depression and Parkinson's disease (e.g. tricyclic antidepressants and MAO inhibitors must therefore not be taken at the same time). (Please note section "2. What you need to know before you use Orabloc").

Please also note the section "Do not use Orabloc" concerning the simultaneous use of certain beta blockers (such as propranolol).

Adrenaline (epinephrine) may inhibit the release of insulin from the pancreas. This may reduce the effect of oral antidiabetics (medicines for the treatment of diabetes).

If Orabloc is used at the same time with certain anaesthetic gases (e.g. halothane), this may trigger heart rhythm disturbances.

Phenothiazines can influence the blood-pressure-increasing effects of adrenaline (epinephrine). Therefore concomitant treatment should be avoided. If concomitant treatment is necessary patients should be monitored carefully.

Please note: In patients treated with blood clot-inhibiting ("blood-thinning") medicines (such as heparin or acetylsalicylic acid), an inadvertent injection into a blood vessel as part of local anaesthesia may lead to serious bleeding and also the tendency to bleed (danger of bleeding) may also be generally increased.

Orabloc with food and drink

After using Orabloc, you should not consume any food until the local anaesthetic has worn off.

Pregnancy and breast-feeding

If you are pregnant, your dentist should use Orabloc only after a careful risk-benefit assessment.

For articaine, there is no experience of use during pregnancy, other than at birth. Animal experimental studies have shown that adrenaline (epinephrine) has a harmful effect on progeny at doses higher than used for dental anesthesia. After administration by mistake of Orabloc to a blood vessel in the mother, a reduction in blood flow to the uterus may occur as a result of the adrenaline (epinephrine) fraction.

If you are pregnant, Orabloc 1:200,000 solution for injection should preferably be used instead of Orabloc 1:100,000
solution for injection; the former contains less adrenaline (epinephrine).

The active ingredients of Orabloc are broken down quickly by your body. This means that quantities of the active ingredients that are harmful to the breastfed infant are not excreted into breast milk. You need not therefore interrupt breastfeeding in connection with short-term treatment with Orabloc.

Driving and using machines

Your dentist will decide when you may drive or use machines again after an intervention. In relevant investigations, no impairment of normal ability to drive was identified after local anaesthetisation with articaine.

Orabloc contains sodium metabisulphite (E223) and sodium.

Sodium metabisulphite (E223) may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How Orabloc is used

Your dentist determines the dosage and method of administration of Orabloc. He will generally be guided by the following recommendations:

Dosage
An injection of 1.8 ml Orabloc per tooth is generally enough for the simple removal of uninflamed upper jaw teeth. In a few cases, a subsequent injection of 1 – 1.8 ml may be necessary to achieve full local anaesthetisation.

Generally, not every tooth needs to be anaesthetised with the full quantity of Orabloc for the removal of neighbouring teeth. The number of injections can normally be reduced.

If an incision or a suture on your palate is necessary, an injection of approx. 0.1 ml per puncture is sufficient. When removing uninflamed front molars in the lower jaw, an injection of 1.8 ml per tooth is generally sufficient. If a full effect does not arise after that, your dentist can give a subsequent injection of 1 - 1.8 ml. Only if the site is not completely anaesthetised even after the subsequent injection your dentist can carry out the otherwise usual anaesthetisation of the entire mandibular nerve.

In the case of jaw surgery, your dentist will dose Orabloc 1:100,000 solution for injection individually according to the seriousness and length of the intervention.

Adults can receive up to 7 mg articaine per kg body weight in the course of a treatment. Quantities of up to 500 mg (equivalent to 12.5 ml solution for injection) are normally tolerated well.

Elderly and patients with severe disturbance of liver and kidney function
In elderly patients and patients with severe disturbance of liver and kidney function (e.g. in the case of nephritis or cirrhosis of the liver), increased quantities of articaine may arise in the blood. If you are in these patient groups, your dentist should take particular care to ensure that the smallest possible quantity for adequate anaesthetisation is used.

Use in children and adolescents

If Orabloc is used in children and adolescents, the minimum volume necessary to achieve adequate anaesthesia should be used. The injection quantity is to be dosed individually according to the child's and adolescent's age and weight. A maximum dose of 5 mg articaine per kg body weight should not be exceeded.
This product has not been studied in children less than 1 year old.

Method of administration
Orabloc is intended for administration in the oral cavity (dental use).
To prevent infections (e.g. transmission of hepatitis), new and sterile syringes and needles must be used for each injection.
For single use. Any unused solution should be discarded.
If discoloured or cloudy, the medicine must not be used.

If you received too much of Orabloc

If excessive quantities of Orabloc are used, disturbances of nervous system function may occur, e.g.:
- drowsiness,
- dizziness,
- nausea,
- clouding of consciousness,
- seizures and disorders of breathing.

Disturbances of cardiovascular function may also arise, such as a fall or rise in your blood pressure. Such disturbances require dental monitoring and possibly suitable therapy by your dentist.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Common (may affect up to 1 in 10 people)
Nausea, vomiting, disturbed sensation of touch (paraesthesia), reduction in sensitivity of sensation in the mouth and facial area (hypoaesthesia); headaches which are presumably attributable to the epinephrine fraction

Uncommon (may affect up to 1 in 100 people)
Rapid heart beat, (tachycardia), dizziness

Unknown (frequency cannot be estimated from the available data)
- Heart rhythm disturbances, increase in blood pressure, drop in blood pressure, lowered heart rate (bradycardia), heart failure and shock (possibly life-threatening).
- Depending on dose (particularly in the case of excessive dosing or inadvertent injection into a blood vessel), disturbances of the nervous system may arise, e.g.:
  - agitation, nervousness,
  - drowsiness ranging to loss of consciousness, coma,
  - respiratory disturbances ranging to respiratory arrest,
  - muscle tremor, muscle twitching ranging to convulsions.
- During or shortly after the injection of local anaesthetics in the head area, temporary visual disorders (blurred vision, blindness, double images) may arise.
- Nerve damage (e.g. of the facial nerve) and a reduction in sensitivity of taste in the mouth and facial area are not side effects that can be induced by Orabloc alone. These side effects may arise in any dental intervention and cannot therefore be ruled out. They are determined by the course of the nerves in the injection area or by defective injection technique.

- An inadequate supply of oxygen to tissue leading to the death of tissue as a result of inadvertent injection into a blood vessel may very rarely arise in the injection area.
- Hypersensitivity reactions (allergic or allergy-like reactions) may arise. These may manifest themselves as swelling or inflammation at the injection site. Hypersensitivity reactions arise that are not restricted to the injection site:
  - reddening,
  - itching,
  - connective tissue inflammation,
  - common cold,
  - facial swelling (in the form of Quincke's oedema) with swelling of the upper and/or lower lip and/or cheeks,
  - swelling of the laryngeal area with a feeling of tightness and swallowing complaints,
  - nettle rash,
  - respiratory complaints ranging to anaphylactic shock.
- Owing to the content of sodium metabisulphite hypersensitivity reactions that may manifest themselves as vomiting, diarrhoea, wheezing, acute asthma attacks, disturbances of consciousness or shock may arise very rarely, particularly in bronchial asthmatics.
- respiratory dysfunction (tachypnea, bradypnea) that may lead to apnea

Additional side effects in children
In young children, compared to adults, there is an increased risk of self-biting, which could result in soft tissue injury, because of prolonged numbness in the area of the mouth after the dental procedure.

If a side effect arises suddenly or develops strongly, inform a doctor immediately. This is particularly important because certain pharmaceutical side effects (e.g. fall in blood pressure or respiratory disturbances) may become life-threatening.

Reporting of side effects
If you get any side effects, talk to your doctor, dentist, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Orabloc

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 carton and on the cartridge after "EXP". The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Orabloc contains

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

- Orabloc 1:100,000
- Articaine hydrochloride and adrenaline (epinephrine) solution for injection*:*

- 1 ml solution for injection contains 40 mg of articaine hydrochloride and 0.01 mg adrenaline (epinephrine) as adrenaline tartrate.
- One cartridge of 1.8 ml of solution for injection contains 72 mg articaine hydrochloride and 0.018 mg adrenaline (epinephrine) as adrenaline tartrate

- The other ingredients are:
  sodium metabisulphite (E223), sodium chloride, hydrochloric acid 2% (for pH adjustment), water for injection.

What Orabloc looks like and contents of the pack

Orabloc is a sterile, clear, colourless solution for injection in clear glass cartridges closed at one end with a bromobutylic rubber plunger and at the other with an aluminium cap and rubber seal.

The cartidge is available in different packages:

The cartridges are packaged in blisters (10 cartridges/blister); the blisters are packaged in a cardboard box containing 5 x 10 or 10 x 10 cartridges.

Each cartridge is assembled in a plastic injector; each injector containing a cartridge is placed in a sealed blister; the injectors are packaged in a cardboard box together with an Instructions for use of the injector: 50 or 100 units per commercial pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Pierrel Pharma S.r.l.
Strada Statale Appia, 46/48
81043 Capua (CE)
Italy

Manufacturer
Pierrel S.p.A.
Strada Statale Appia, 7 BIS 46/48
81043 Capua (CE)
Italy

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