

# ARTICAINE MEDIS® with adrenaline 1/100 000

## Solution for injection for dental use

### Articaine hydrochloride / Adrenaline

#### Please read carefully the integrity of this notice before taking this drug.

- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If use of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

#### In the leaflet:

1. What is ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use and what is used for?
2. What you need to know before you use ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?
3. How to use ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?
4. Possible side effects?
5. How to store ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?
6. Further information.

#### 1. WHAT IS ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use and what is used for?

**Pharmacotherapeutic class:**  
LOCAL ANESTHETIC / ARTICAINE

**Therapeutic indications:**  
This medication is indicated for adults and children over 4 years, for local or loco-regional anesthesia in dentistry practice.

#### 2. What you need to know before you use ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?

**List of information needed before taking the medication**

Not applicable.

#### Contraindications

#### Do not use ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use

This medication MUST NOT BE USED in case of hypersensitivity (allergy) to local anesthetics or any of the ingredients in this product and in the following situations:

- severe and uncomplicated atrioventricular conduction disorders;
- epilepsy not controlled by treatment;
- acute intermittent porphyria.

This medicine SHOULD NOT BE USED unless otherwise directed by a doctor, when treated with guanethidine and related products (antiglaucoma medications).

#### Precautions for use; special warnings

Take special care with ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use.

#### Special warnings

THIS PRODUCT CONTAINS ADRENALINE at 1/100 000.

Consider the risk of local necrosis in hypertensive or diabetic subjects.

• risk of anesthesiophagia: various bites (lips, cheeks, mucous membranes, tongue); warn the patient from chewing gum or food as long as incoercibility persists.

The use of this product is not recommended in children under 4 years, due to the anesthetic technique that is not adapted before this age.

Avoid injection into infected and inflammatory areas (decreased effectiveness of local anesthetic)

#### Precautions for use

**Use of this product requires first:**

- a clinical questioning to know the patient's pathology, the current therapies and the patient's history;
- perform a test injection of 5 to 10% of the dose in case of allergic risk;
- perform the injection slowly and strictly out of the vessels guided by repeated aspirations;
- maintain verbal contact with the patient

Monitoring should be increased in subjects on anticoagulants (INR monitoring).

Due to the presence of adrenaline, increased precautions and monitoring in the following cases:

- all rhythm disorders, except for bradycardia;
- coronary heart disease;
- severe hypertension.

In case of severe hepatic impairment, it may be necessary to reduce doses of articaine, because of the mainly hepatic metabolism of amide local anesthetics.

The posology should also be decreased in case of hypoxia, hyperkalemia or metabolic acidosis.

Simultaneous administration of this anesthetic with certain medications (see Interactions with other drugs) requires careful monitoring of the clinical and biological status of the patient.

#### Using other medicines

#### Taking or using other medicines

The combination with guanethidine and related drugs (antiglaucoma medications) is absolutely not recommended.

Precautions for use under strict medical control are necessary with:

- all classes of antidepressant medications: MAOIs (propylidone, moclobemide, tolaxalone), imipramine, serotonergic and nonadrenergic (described for miltacipran and venlafaxine), the intake of which must be limited; for example: less than 0.1 mg of adrenaline in 10 minutes or 0.3 mg in one hour in adults;
- volatile halogenated anesthetics (increased cardiac reactivity), whose contribution must also be limited; for example: less than 0.1 mg adrenaline in 10 minutes or 0.3 mg in one hour in adults.

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription, tell your doctor or pharmacist.

#### Interactions with food and drinks

Not applicable.

#### Interactions with herbal products or alternative therapies

Not applicable.

#### Use during pregnancy and lactation

#### Pregnancy and lactation

The use of this medication should be considered during pregnancy only when absolutely necessary.

Continued breastfeeding is possible after the dental anesthesia.

Ask your doctor or pharmacist for advice before taking any medicine.

#### Sport

The attention of athletes should be drawn to the fact that this drug may induce a positive reaction of certain tests performed during anti-doping tests.

#### Effects on ability to drive or use machinery

#### Driving and using machinery

This product may affect response capabilities for vehicle driving or machinery utilization.

#### List of excipients with known effect

List of excipients with known effect: sodium.

#### 3. HOW TO USE ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?

#### Instructions for good usage

Not applicable.

#### Posology, Method and / or Route (s) of Administration, Frequency of Administration and Duration of Treatment

#### Posology

Reserved for adults and children over 4 years old.

#### In the adult

The quantity to be injected will be adapted according to the importance of the intervention.

Typically, one half to one cartridge for routine surgery.

Do not exceed the dose of 7 mg articaine hydrochloride per kilogram of body weight.

#### Child (over 4 years old)

The quantity injected depends on the age, the weight of the child and the type of intervention to be performed.

The maximum dose is 5 mg of articaine hydrochloride (0.125 ml of anesthetic solution) per kilogram of body weight.

The average dose in mg of articaine hydrochloride, which can be administered in children, can be calculated as follows: Weight of the child (in kilograms) × 1.33.

#### Elderly

Half of the dose reserved for adults

#### Method and route of administration

LOCAL OR REGIONAL INTRA-ORAL SUBMUCOSAL INJECTION.

Verify that there is no vascular intrusion by repeated aspiration tests, especially during regional (truncular) anesthesia.

The injection speed must not exceed 1 ml of solution per minute.

#### Instructions for use, handling instructions

As with any cartridge, the diaphragm will be disinfected just before use. It will be carefully stamped:

- whether with 70% ethyl alcohol,
- or with 90% pure isopropyl alcohol for pharmaceutical use.

The cartridges must never be immersed in any solution whatsoever.

Do not mix the solution for injection in one syringe with other products.

Any cartridge of anesthetic solution that has been started should not be reused.

#### Duration of treatment

Single use.

#### Symptoms and instructions in case of overdose

If you have used more ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, than that you should have:

Toxic reactions, indicating an overdose of local anesthetic, may occur under two conditions

- immediately, caused by accidental intravascular injection
- or later, caused by true overdose following an injection of excessive quantity of anesthetic solution

#### Actions to be taken

As soon as the warning signs appear, ask the patient to hyperventilate, lying down if necessary.

Upon the occurrence of convulsions, oxygenation, injection of a benzodiazepine.

Treatment may require intubation with assisted ventilation.

Instructions in case of omitting one or more doses

Not applicable.

#### Risk of withdrawal syndrome

Not applicable.

#### 4. Possible side effects?

#### Description of adverse effects

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

As with all anesthetics used in dentistry, faintness can occur.

Due to the presence of sodium diulfate, risk of allergic reactions including generalized allergic reaction with respiratory discomfort.

#### In case of overdose or in certain predisposed patients, the following clinical signs may be observed:

#### • On the central nervous system:

nervousness, agitation, yawning, trembling, apprehension, nystagmus, logorrhoea, headache, nausea, tinnitus.

These warning signs require asking the patient to hyperventilate, as well as careful monitoring to prevent possible aggravation with convulsions then depression of the CNS

#### • On the respiratory system:

tachypnea then bradypnea can lead to apnea.

#### • On the cardiovascular system:

tachycardia, bradycardia, cardio-vascular depression with hypotension that may lead to collapse, rhythm disturbances (ventricular extrasystoles, ventricular fibrillation), conduction disturbance (atrioventricular block).

These cardiac manifestations can lead to cardiac arrest.

#### Other rare side effects due to articaine:

Alteration of nerve transmission (para, hypo and dyesthesia) may occur after administration of articaine. Recovery is usual but can be long, sometimes requiring more than two months.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or dentist. This also applies to any undesirable effect that is not mentioned in this leaflet. You can also report side effects directly through the national reporting system.

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

#### 5. How to store ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use?

Keep out of the reach and sight of children.

#### Expiration date

Do not use ARTICAINE MEDIS 40 mg / ml ADRENALINEE 1/100 000, solution for injection for dental use after the expiry date which is stated on the box.

#### Storage conditions

After opening: the product should be used immediately.

Store at a temperature not exceeding 25°C.

Keep cartridges in the outer packaging in order to protect from light.

Avoid any risk of freezing.

#### If necessary, warn against some visible signs of deterioration

Medications should not be thrown away to the sewer or household garbage. Ask your pharmacist what to do with unused medications. These measures will help protect the environment.

#### 6. Further information

What ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, contains

#### Active substances are:

Articaine hydrochloride.....40.000 mg

Adrenaline.....0.010 mg

as adrenaline tartrate

In a solution of 1 ml.

A 1.8 ml cartridge contain 72.000 mg of Articaine hydrochloride and 0.018 mg of adrenaline.

#### Excipients are:

Sodium chloride, sodium metabisulfite, sodium edetate, water for injection.

What ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, looks like

#### and contents of the pack

ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, solution for injection for dental use, cartridge of 1.8 ml , pack of 50 cartridges.

Marketing authorization number: 9233961.

#### Delivery conditions: list 1

#### Marketing authorization holder and manufacturer:

Les laboratoires Médis

Tunis route km 7 - PB. 206 - 8000 Nabeul, Tunisia.

Tel : +216 72 235 006

Fax : +216 72 235 016

E-mail : contact@labomedis.com

#### What ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, looks like

#### and contents of the pack

ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, solution for injection for dental use, cartridge of 1.8 ml , pack of 50 cartridges.

Marketing authorization number: 9233961.

#### Excipients are:

Sodium chloride, sodium metabisulfite, sodium edetate, water for injection.

What ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, looks like

#### and contents of the pack

ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, solution for injection for dental use, cartridge of 1.8 ml , pack of 50 cartridges.

Marketing authorization number: 9233961.

#### Delivery conditions: list 1

#### Marketing authorization holder and manufacturer:

Les laboratoires Médis

Tunis route km 7 - PB. 206 - 8000 Nabeul, Tunisia.

Tel : +216 72 235 006

Fax : +216 72 235 016

E-mail : contact@labomedis.com

#### What ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, Solution for injection for dental use, looks like

#### and contents of the pack

ARTICAINE MEDIS 40 mg/ml with adrenaline 1/100 000, solution for injection for dental use, cartridge of 1.8 ml , pack of 50 cartridges.

Marketing authorization number: 9233961.

This leaflet was last updated in December 2018.

#### This is a Medicament

- Medicament is a product but not like the others.
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children