Package leaflet: Information for the patient

Lidokain/Adrenalin Aguettant 10 mg/ml + 5 micrograms/ml solution for injection
Lidokain/Adrenalin Aguettant 20 mg/ml + 5 micrograms/ml solution for injection
lidocaine hydrochloride / adrenaline

Read all of this leaflet carefully before you are given 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

<Invented name> contains the active substance lidocaine hydrochloride which is a local anaesthetic and the active substance adrenaline which prolongs the effect of lidocaine. The medicine is used to numb parts of the body during surgical procedures. It temporarily blocks the nerve signals in the area where it is injected from being able to pass pain messages to the brain, which prevents you from feeling pain.

<Invented name> 10 mg/ml + 5 micrograms/ml can be used in adults and children over 1 year of age.
<Invented name> 20 mg/ml + 5 micrograms/ml can be used in adults and adolescents over 12 years of age.

2. What you need to know before you are given <Invented name>

<Invented name> should not be given:
- if you are allergic to lidocaine, other local anaesthetics similar to lidocaine, adrenaline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to sulphite.
- for anaesthesia via the membranes surrounding the spinal cord (epidural anaesthesia) if you have very low blood pressure, for example in the event of shock following heart failure (cardiogenic shock) or a significant reduction in blood circulation in the body following significant blood or fluid loss (hypovolaemic shock).
- for anaesthetising fingers, toes, nose, ears or penis.

Warnings and precautions
Talk to your doctor or nurse before <Invented name> is given to you:
- if you have heart disorders including disorders in the heart's electrical conduction system, slow or irregular heartbeat (heart block) and chest pain (angina)
- if you are elderly or in a generally debilitated condition
- if you have severe high blood pressure or untreated high blood pressure
- if you have porphyria (a disease based on a disorder in the production of red blood cell pigment)
- if you have severely reduced liver or kidney function

- if you have an overactive thyroid gland
- if you have diabetes
- if you have reduced blood supply to the brain
- if you have been treated with a local anaesthetic before and did not respond well to it at the time
- if you are being treated with certain medication for heart rhythm disorders, such as amiodarone.

Children and adolescents
<Invented name> 10 mg/ml + 5 micrograms/ml should not be used for children below 1 year of age.
<Invented name> 20 mg/ml + 5 micrograms/ml should not be used in childen less than 12 years of age.

Other medicines and <Invented name>
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

The following medicines may influence the effect of <Invented name>.
In particular, tell your doctor if you are taking any of the following:
- medicines used to treat heart disorders including irregular heartbeats, high blood pressure and chest pain (angina), such as beta blockers (e.g. metoprolol, propranolol) or calcium channel blockers (e.g. amiodarone);
- medicines used to relax muscles during general anaesthesia (e.g. suxamethonium);
- medicines that reduce your level of consciousness, such as sleeping pills and medicines for treatment of anxiety (sedatives);
- tricyclic antidepressants (medicines to treat depression) or ergotamine as this can cause persistent high blood pressure;
- medicines that increase the risk of getting seizures (e.g. tramadol, bupropion);
- medicines that decrease the risk of getting seizures (e.g. diazepam);
- cimetidine, a medicine used to treat heartburn;
- antivirals medicines (e.g. ritonavir), macrolides antibiotics (e.g. erythromycine) or antifungals (e.g. ketoconazole, itraconazole);
- ciprofloxacin (antibiotics);
- medicines used to treat epilepsy (phenobarbital, phenytoin, carbamazepine or primidone);
- fluvoxamine, a medicine used in the treatment of mental illness;
- other anaesthetics, including local anaesthetics;
- diuretics (water tablets) (acetazolamide, loop diuretics or thiazides);
- general anaesthesia by inhalation, such as halothane, as this may cause severe cardiac arrhythmias.
- antipsychotic medicines (e.g. phenothiazines, butyrophenones); as they reduce the effect of adrenaline on blood pressure.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before being given this medicine.

Pregnancy
Lidocaine passes the placenta and reaches the foetus. However, there is no evidence that lidocaine causes negative effects on the foetus, even if the risk is not fully known.
Adrenaline can potentially reduce uterine blood flow and hinder contractions during childbirth, especially after accidental injection into the mother's blood vessels.
Your doctor will weigh the benefits against the risks of using this medicine for short term treatment during pregnancy. If the medicine is used at the cervix, the doctor will monitor the baby’s heart rate closely.

Breast-feeding
Lidocaine and adrenaline pass into breast milk, but are unlikely to have any effects on breastfed babies. When deciding if you can breast-feed the doctor will however weigh your need for treatment and the benefits of breast-feeding against the potential risks to the child.

Driving and using machines

This medicine may affect your ability to drive or operate machines. After receiving this medicine you may experience impact on your motor skills and mobility. Do not drive or use machines until these effects have disappeared.

<Invented name> contains sodium and sodium metabisulfite (E223).
<Invented name> contains 2.48 mg of sodium (main component of cooking/table salt) per ml. This is equivalent to 1.24% of the recommended maximum daily dietary intake of sodium for an adult.

Presence of sodium metabisulfite may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm.

3. How <Invented name> is given to you

This medicine will be given to you by your doctor or nurse, who will decide the correct dose which depends on the type of anaesthetic you need, the area to be anaesthetised and the required duration of the anaesthesia. It will also depend on your weight, age and physical condition. You will be given the lowest concentration and smallest dose possible to produce the required effect.

This medicine will be given to you as an injection. The part of the body where it will be used will depend on why you are being given this medicine.

Use in children and adolescents
<Invented name> 10 mg/ml + 5 micrograms/ml should not be used for children below 1 year of age.
<Invented name> 20 mg/ml + 5 micrograms/ml should not be used in children less than 12 years of age because of safety concerns.

If you have been given too much <Invented name>
Since this medicine is administered to you by a trained healthcare professional, it is unlikely that you will be given too much of this medicine.

Nevertheless, if you think you have been given too much medicine, or you begin to experience dizziness or lightheadness, headache, numbness of the tongue, a ringing in the ear, nausea, vomiting or shivering, you must tell the person giving you the injection immediately. Your doctor will know how to manage these symptoms and give you any necessary treatment.

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

4. Possible side effects

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

Some side effects may be serious. Seek immediately medical help if you have an allergic reaction causing:
- swelling of the hands, feet, face, lips, mouth, tongue or throat
- difficulties in breathing
- itchy skin rash
- fever
- drop in blood pressure and shock

These side effects are rare (may affect up to 1 in 1,000 people).

Other side effects may include:

Very common (may affect more than 1 in 10 people)
- nausea.

Common (may affect up to 1 in 10 people)
- sensation of tickling, tingling, burning, pricking, or numbness (paresthesia)
- loss of consciousness
- slow hear beat
- low blood pressure or high blood pressure
- vomiting.

Uncommon (may affect up to 1 in 100 people)
- Signs of poisoning reactions in the central nervous system, such as tingling or numbness around the mouth, numbness of the tongue, increased sensitivity to sound, difficulty in speaking

Rare (may affect up to 1 in 1,000 people)
- changes in sensations or muscle weakness (neuropathy)
- convulsions (seizures)
- partial paralysis
- persistent anaesthesia
- headache accompanied by a ringing or clicking sound in your ears (tinnitus) and an abnormal intolerance to light (photophobia)
- hearing loss (deafness)
- damages of your brain nerves
- drop of your eyelid(s) combined with the narrowing of your pupils and sometimes decreased sweating (Horner's syndrome). It may occur after application in the head/neck region
- asymmetric sweating and flushing of the upper chest, neck or face (Harlequin syndrome)
- irregular heartbeats
- reduced cardiac function, cardiac arrest (heart stops suddenly)
- double vision
- slowed or stopped breathing
- skin rash or hives
- swelling due to accumulation of fluid.

Frequency Not known (cannot be estimated based on available data)
- bluish discoloration of the skin, headaches, shortness of breath and tiredness due to abnormal quantities of methaemoglobin (a form of haemoglobin which has a reduced capacity to bind oxygen) in the blood (methaemoglobinaemia).

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

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 ampoule label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Keep the ampoule in the outer carton in order to protect from light. This medicine may be stored at temperatures not exceeding 25 °C for a maximum period of 3 months. In all cases, once initially removed from refrigerated storage, the medicine should be discarded after 3 months.

After opening, the medicine must be used immediately. Any unused solution must be discarded.

Do not use this medicine if you notice visible signs of deterioration. Only clean and colourless solution free from particles or precipitates should be used.

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

6. Contents of the pack and other information

What <Invented name> contains

- The active substances are lidocaine hydrochloride and adrenaline.
  <Invented name> 10 mg/ml + 5 micrograms/ml:
  Each ml of solution for injection contains lidocaine hydrochloride monohydrate equivalent to 10 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 5 micrograms of adrenaline (epinephrine).
  Each 10 ml ampoule contains lidocaine hydrochloride monohydrate equivalent to 100 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 50 micrograms of adrenaline (epinephrine).

  <Invented name> 20 mg/ml + 5 micrograms/ml:
  Each ml of solution for injection contains lidocaine hydrochloride monohydrate equivalent to 20 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 5 micrograms of adrenaline (epinephrine).
  Each 10 ml ampoule contains lidocaine hydrochloride monohydrate equivalent to 200 mg of lidocaine hydrochloride and adrenaline (epinephrine) tartrate equivalent to 50 micrograms of adrenaline (epinephrine).

- The other ingredients are sodium chloride, concentrated hydrochloride acid (for pH-adjustment), sodium hydroxide (for pH-adjustment), sodium metabisulfite (E223), water for injections (see section 2 “<Invented name> contains sodium and sodium metabisulfite (E223)”).

What <Invented name> looks like and contents of the pack

This medicine is a clear and colourless aqueous solution for injection (injection) practically free from particles. The solution is contained in a colourless glass ampoule filled with 10 ml. Each pack contains 10 ampoules.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

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