Package leaflet: Information for the patient

Lidokain Aguettant 20 mg/ml, solution for injection/infusion
lidocaine hydrochloride

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist 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.

<Invented name> is used in adults to numb part of the body during small surgical procedures.
It stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain.

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

You must not be given <Invented name>:
- if you are allergic to lidocaine hydrochloride, to local anaesthetics of the amide type or any of the other ingredients of this medicine (listed in section 6).
- if you have very low blood pressure, or if you have lost too much blood or other body fluids or your heart is unable to pump enough blood for other reasons, you should not get <Invented Name> injected into your spine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given <Invented name>:
- if you are elderly or in a generally debilitated condition.
- if you have heart disorders including disorders in the heart's electrical conduction system, heart block , slow heartbeat, and heart failure.
- if you have lung or breathing disorder.
- if you have any kidney or liver disease.
- if you have epilepsy. Your doctor will monitor you closely for manifestation of symptoms.
- if you have porphyria.
- if you have or are treated for, bleeding disorders .
- if you are in the last three months of pregnancy.

Additionally your doctor knows that an injection of this medicine into inflamed tissue may lead to an increased uptake of the active substance into the blood system and the effect of the active substance on your body will be weakened.

Your doctor will consider that there is an increased risk of side effects on the nervous system if this medicine is administered in the head and neck region.

Children and adolescents
<Invented name> should not be used in children.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. <Invented name> may affect or be affected by other medicines.

Tell your doctor if you are taking any of the following:
- medicines used to treat high blood pressure such as diuretics (water tablets);
- medicines used to treat heart disorders including irregular heartbeats, such as beta blockers (e.g. metoprolol, propranolol) or calcium channel blockers (e.g. amiodarone);
- medicines that narrow your blood vessels (vasoconstrictors, e.g. epinephrine, norephinephrine);
- medicines used to relax muscles during general anaesthesia (e.g. suxamethonium);
- sleeping pills and medicines that reduce your level of consciousness (sedatives);
- medicines that increase the risk of getting fits and seizures (e.g. tramadol, bupropion);
- medicines that decrease the risk of getting fits and 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;
- medicines used to reduce pressure within the eye (e.g. acetazolamide);
- other anaesthetics, including local or volatile anaesthetics.

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, pharmacist or nurse for advice before being given this medicine. Then your doctor will decide if you should be given this medicine.

Pregnancy
Your doctor will only administer this medicine while you are pregnant or during delivery if he/she considers it necessary. Lidocaine crosses the placenta, and if use for short term paracervical blockade or pudendal blockad during pregnancy or delivery, the heart rate of the foetus will be carefully monitored due to increased risks of changed heart beat.

Breast-feeding
Lidocaine passes into human breastmilk in small amounts. The use of lidocaine at recommended doses is unlikely to affect the breast-fed child. Breast-feeding can therefore be continued during use of lidocaine.

Driving and using machines
<Invented name> may affect your ability to drive or operate machines. Depending on dose and method of administration, lidocaine can have a temporary effect on your motor function and coordination, that may affect your capacity to drive or use machine.

Your doctor should advise about when it would be safe to drive or operate machines.

<Invented name> contains sodium
This medicine contains 101 mg of sodium (main component of cooking/table salt) in each vial of 50 ml (equivalent to 2.02 mg/ml). This is equivalent to 5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How <Invented name> is given

<Invented name> will be given to you by or under the supervision of, a doctor. It will be given to you as a regional (not systemic) injection into a vein, under the skin, or into the epidural space near the spinal cord.
The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, physical condition and the part of your body that the medicine is being injected into. You will be given the smallest dose possible to produce the required effect.

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

Whether you develop symptoms of an overdose or not depends on the level of this medicine present in your blood. The more lidocaine that is in your blood and the more rapidly it is given to you, the more frequently and severely you might experience symptoms of an overdosage.
Side effects that do occur will disappear in most cases after stopping lidocaine administration.

If you think that you have received too much of the medicine, contact a doctor or nurse immediately.
The first signs of being given too much <Invented name> are usually as follows:
- Euphoria, apprehension, hallucination
- Feeling dizzy or light-headed,
- Vertigo,
- Headache,
- Yawning,
- Excessive speech production (loghorrea)
- Nausea, vomiting,
- Numbness or tingling sensations of the lips and around the mouth,
- Muscular twitching,
- Problems with sight and hearing.

These are signs of alarm necessitate attentive surveillance: muscular twitching, tremors, shivering, and generalised seizures. Coma and stopping breathing for a short while (apnoea).

Cardiovascular toxicity may be seen in severe cases, such as cardiac rhythm disorders, unpalpable pulse, decrease in cardiac contractility, hypotension and possibly cardiac arrest.
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
- 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
- pain or shivering due to injections
- slow heart beat
- low blood pressure or high blood pressure
- vomiting

Rare (may affect up to 1 in 1,000 people)
- changes in sensations or muscle weakness (neuropathy)
- convulsions (seizures)
- partial paralysis
- 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 occurs after application in the head/neck region
- asymmetric sweating and flushing of the upper chest, neck or face (Harlequin syndrome)
- irregular heartbeats
- cardiac arrest
- double vision
- slowed or stopped breathing
- skin rash or hives

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, pharmacist 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 Appendix V. 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.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. Your doctor or nurse will check this.

For single use only.
Do not use this medicine if you notice the presence of particles.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What <Invented name> contains
The active substance is lidocaine hydrochloride.

- Each ml of solution for injection/infusion contains 20 mg of lidocaine hydrochloride (equivalent to 21.33 mg of lidocaine hydrochloride monohydrate).
- Each 50 ml vial of solution for injection/infusion contains 1000 mg of lidocaine hydrochloride (equivalent to 1066.5 mg of lidocaine hydrochloride monohydrate).

The other ingredients are sodium chloride, sodium hydroxide (for pH adjustment) and water for injections.

What <Invented name> looks like and contents of the pack
This medicine is a clear colourless solution for injection/infusion, in a 50 ml clear glass vial closed with a chlorobutyl rubber stopper and an aluminium flip-off seal.

<Invented name> is available in box of 1 or 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
[To be completed nationally]

This leaflet was last revised in MM/YYYY.

Other sources of information

Detailed information on this medicine is available on the website of {National Agency link}.

The following information is intended for healthcare professionals only:

Method of administration
<Invented name> should only be used by, or under the supervision of, doctors with experience of regional anaesthesia and resuscitative skills. Facilities for resuscitation should be available when administering local anaesthetics.

Concomitant administration of intravenous lidocaine and local anaesthetics should be avoided.

Please refer to the summary of product characteristics for posology information.

For single use only, used immediately after first opening, discard any unused contents.
Do not use this medicine if you notice the contents are discoloured in any way. The solution for injection should not be used if there are particles present.

Treatment of an overdose
If signs of acute toxicity occur during administration of the local anaesthetic, administration of the anaesthetic should be stopped immediately. Intravenous fluid should be given in order to prevent hypoxia and acidosis, which potentiate local anaesthetic systemic toxicity (LAST) and exacerbate progression to cardiovascular collapse and seizure.

If convulsions occur, oxygenation should be maintained and circulation should be supported. If required, an anticonvulsant should be administered. Use of intravenous lipid emulsion should be considered.
If cardiovascular depression is evident (hypotension, bradycardia) treatment with intravascular fluid substitution, vasopressoric, chronotropic and/or inotropic drugs should be taken in consideration.
In case of circulatory arrest, immediate cardiopulmonary resuscitation should be initiated. For a successful outcome, prolonged resuscitative efforts may be required.

Patients having manifested signs of LAST should be monitored for at least 12 hours, because cardiovascular depression can persist or recur after treatment.

Centrally acting analeptics are contra-indicated.

There is no specific antidote.
Lidocaine cannot be eliminated by haemodialysis.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special storage conditions
Chemical and physical in-use stability has been demonstrated for 2 days at 30°C in a polypropylene syringe. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would not be longer than 24 hours at 2 to 8°C, unless reconstitution /dilution has taken place in controlled and validated aseptic conditions.