Package leaflet: Information for the patient

Bupivacaine Spinal Tung Aguettant 5 mg/ml solution for injection
bupivacaine 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.
- If you get any side effects, talk to your doctor. 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 bupivacaine hydrochloride. It is a local anaesthetic used to numb (anaesthetise) the lower parts of the body during surgery in adults and children of all ages. It is used, for example, to numb legs to be operated on, in urological surgery or in lower abdominal surgery.

The medicine temporarily blocks the nerve signals in the area where it is injected and it temporarily reduces or removes the sensation in certain parts of the body.

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

<Invented name> should not be given:
- if you are allergic to bupivacaine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other local anaesthetics of the same class (such as mepivacaine, lidocaine)

Intrathecal anaesthesia should not be given if:
- you have acute active diseases of the brain or spine, such as meningitis, polio or spondylitis
- you have a severe headache caused by bleeding inside the head (intracranial haemorrhage)
- you have blood poisoning (septicaemia)
- you have a purulent infections at or near the injection site
- you have had a recent trauma (such as a fracture of the vertebral column)
- you have tuberculosis or a tumour of the spine
- you have spinal stenosis (narrowing of the spinal cord)
- you have a serious condition where the heart is unable to supply enough blood to the body (cardiogenic shock)
- you have very low blood pressure leading to collapse (hypovolaemic shock)
- your blood does not clot properly or if you are taking medicines to prevent blood clots
- you have problems with your spinal cord due to anaemia.

Warnings and precautions
Talk to your doctor before <Invented name> is given to you:
- if you have a type of arrhythmia in your heart called AV block II or III
- if you have liver problems
- if you have kidney problems
- if you are elderly or have a debilitated general condition
- if you are pregnant (especially in later stages of pregnancy)
- if you have a heart disease (aortic stenosis)
- if you have chronic back pain
- if you have pre-existing headache
- if you have low blood pressure (hypotension)
- if you have persistent sensations like numbness, tingling, pins and needles (paresthesia).

Neurological diseases are not thought to be aggravated by the anaesthesia, but caution should be exercised.

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

<Invented name> can interact with other medicines, such as:
- other local anaesthetics
- medicines structually similar to <Invented name>, such as medicines for heart arrhythmias (antiarrhythmics).

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 for advice before this medicine is given to you.

<Invented name> can be used during pregnancy and breast-feeding. The dose will be adjusted by your doctor if you are in the late stage of pregnancy.

Driving and using machines
You should not drive or use machines on day of surgery since <Invented name> can affect your reaction ability and muscle coordination.

<Invented name> contains sodium
This medicine contains less than 1 mmol of sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How <Invented name> is given to you

<Invented name> will be given to you by your doctor, who will decide the correct dose. It will be given to you as an injection into the lower part of your spine.

Dosage depends on type of surgery, the age and weight of the patient and it will be determined by your doctor.

Use in children and adolescents
<Invented name> is injected slowly into the spinal channel (part of the spine) by a doctor experienced in child anaesthesia.

If you have been given too much <Invented name>
It is unlikely that you will receive too much of this medicine since you will receive it in hospital and by health care staff. If you are worried that you have been given too high dose or if you have any questions about the dose you have been given, talk to your doctor.

The first signs of being given too much <Invented name> are usually as follows:
- Low blood pressure
- Slow pulse
- Irregular heartbeat
- Feeling dizzy or light-headed
- Numbness of the lips and around the mouth
- Numbness of the tongue
- Hearing problems
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you <Invented name> as soon as these signs appear.

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

4. Possible side effects

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

Serious side effects
If you experience the following symptoms, contact a doctor **immediately**:
- Signs of intoxication reactions in the central nervous system, such as numbness, tingling, loss of movement (paresis), muscle weakness or dysesthesia (abnormal sensation) (uncommon side effects, may affect up to 1 in 100 people)
- Your heart suddenly stops beating unexpectedly and you lose consciousness (cardiac arrest) (rare side effect, may affect up to 1 in 1,000 people)
- Slow and shallow breathing (respiratory depression) (rare side effect, may affect up to 1 in 1,000 people)
- Severe allergic reaction with symptoms such as difficulty breathing, swelling of the lips, throat and tongue and low blood pressure (anaphylactic shock) (rare side effects, may affect up to 1 in 1,000 people)

Other side effects
Very common (may affect more than 1 in 10 people)
- Nausea (feeling sick)
- Low blood pressure
- Slow heartbeat (bradychardia)

Common (may affect up to 1 in 10 people)
- Headache
- Vomiting (being sick)
- Difficulty passing urine (urinary retention)
- Involuntary urination (urinary incontinence)

Uncommon (may affect up to 1 in 100 people)
- Back pain
- Tingling, burning sensation or numbness of skin (paraesthesia)

Rare (may affect up to 1 in 1000 people)
- Unintentional block of nerves in the spine (spinal block) which can cause a temporary loss of feeling in the abdomen and/or the lower part of the body, respiratory depression and even loss of consciousness
- Double sided paralysis, often in lower part of body or in both legs (paraplegia)
- Pain and sense disturbances due to nerve inflammation (neuropathy)
- Loss of voluntary movement (paralysis)

- Inflammation of a membrane surrounding the spinal cord (arachnoiditis) which can cause pain in the lower back, or pain, numbness or weakness in the legs
- Allergic reactions

Reporting of side effects
If you get any side effects, talk to your doctor. 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 carton, on the blister and on the ampoule label after EXP. The expiry date refers to the last day of that month.

After opening, the medicine must be used immediately.

Do not use this medicine if you notice that the contents are discoloured in any way or if particles or precipitates are present.
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 protect the environment.

6. Contents of the pack and other information

What <Invented name> contains

- The active substance is bupivacaine hydrochloride.
  Each ml contains bupivacaine hydrochloride monohydrate equivalent to 5 mg of bupivacaine hydrochloride.
  Each 4 aml ampoule contains bupivacaine hydrochloride monohydrate equivalent to 20 mg of bupivacaine hydrochloride.
- The other ingredients are glucose monohydrate, sodium hydroxide (pH adjustment) and water for injections.

What <Invented name> looks like and contents of the pack
<Invented name> is a clear, colourless solution for injection in a colourless glass ampoule. Each pack contains 5 ampoules each containing 4 ml solution. The ampoules are packaged in a sealed blister pack with a peelable blister lid.

Marketing Authorisation Holder and 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]

This leaflet was last revised in 2024-12-03