PACKAGE LEAFLET: Information for the patient

PRODIVAKAINE 5

Solution for injection – 5 mg / ml

(Bupivacaine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine!

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. WHAT PRODIVAKAINE 5 IS AND WHAT IT IS USED FOR

Prodivakaine 5 contains the active substance bupivacaine hydrochloride. Bupivacaine hydrochloride is a drug used for local infiltration anaesthesia. It is a homolog of local anaesthetics containing aminoacyl group and has more advantages than other local anaesthetics because it has a more prolonged action.

It has a slow onset of action, after 30 minutes, but it has a long duration of action.

Prodivakaine 5 is used:

- as a local anaesthetic;

- as analgesic in surgery or in oral and dental surgery procedures;
- in diagnostic and therapeutic procedures;
- as epidural analgesic for pain relief;
- in therapies prior to surgery;
- in obstetric anesthesia;
- after trauma.

Prodivakaine 5 (vial 20 ml) because of the methylhydroxybenzoate content should not be used for caudal, epidural, or spinal block.

2. BEFORE YOU TAKE PRODIVAKAINE 5

Do not take Prodivakaine 5 if you:

- are hypersensitive to bupivacaine hydrochloride or to any other ingredient of the drug, because hypersensitivity reactions may appear;
- are hypersensitive to other local anaesthetics of the same group (such as: lidocaine or ropivacaine);
- have complete heart block;
- have inflamed or infected skin adjacent to the injection site;
- have cardiogenic shock (a serious condition when the heart is unable to supply enough blood throughout the body);
- have hypovolemic shock (very low blood pressure, that may cause collapse);
- have coagulation disorders or are taking anticoagulants;
- suffer from meningitis;
- have frequent headache caused by internal beeding (intracranial haemorrhage);
- have spinal cord disorders;
- suffer from anaemia;
- have had recent trauma, tuberculosis or spinal cord cancer.

Bupivacaine **is contraindicated** for use in intravenous regional anaesthesia (Bier's block) and for paracervical block in obstetrics.

Prodivakaine 5 (vial 20 ml) because of the methyl hydroxybenzoate content should not be used for caudal, epidural, or spinal block.

Take special care with Prodivakaine 5

Talk to your doctor before taking Prodivakaine 5 if you:

- suffer from liver disease or severe renal dysfunction;
- suffer from heart disease, mainly those concerning its rythm and if the conduction is impaired;
- suffer from severe shock or low blood pressure;
- suffer from memory loss because of the age;
- have breathlessness because of fluids or a mass in the abdomen;
- have high blood pressure or cerebral blood circulation disorders;
- have low circulating fluids in the body, which causes symptoms such as: sweating, mental confusion, drowsiness or fainting (for example: because of dehydration or large blood loss);
- suffer from porphyria;
- suffer from septicaemia;
- are taking anti-arrhythmic drugs clas III (e.g. amiodarone); you should be under close surveillance and ECG monitoring, since cardiac effects may be additive;
- suffer from *Myasthenia Gravis*;
- suffer from epilepsy.

Prodivakaine 5 should be given with extreme caution to the elderly, children, debilitated patients. If you are not sure, talk to your doctor before taking this drug.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, incuding those obtained without a prescription.

Remember to tell your doctor about the treatment with Prodivakaine 5 if you are given another drug during treatment, because Prodivakaine 5 may have an effect on the action of other dugs or some drugs may affect on its action.

It is especially important for your doctor to know that you have been treated or are being treated with local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. certain

anti-arrhythmics, such as lidocaine and mexiletine, since the systemic toxic effects are additive.
You should also tell your doctor, if you are taking class III anti-arrhythmic drugs, such as amiodarone. Even though specific interaction studies with bupivicaine have not been performed, they should be taken with caution.
There is an increased risk of bupivacaine toxicity when it is given with propranolol.

Pregnancy and breastfeeding

Category C.
Bupivacaine crosses the placenta.
Inform your doctor if you are pregnant, planning to get pregnant or are breastfeeding.
This drug should not be used during pregnancy, unless the benefit outweighs the potential risk to which the fetus is exposed.
Bupivicaine enters the mother's milk in small quantities and it is not expected to affect the child if taken at therapeutic dose levels, however, it should be used with caution.

Driving and using machines

Bupivacaine causes a feeling of drowsiness, for this reason it should be given with caution to see the way it affects anyone.
If bupivacaine is taken, the patient should not drive or use machines until the next day.

Important information about some of the ingredients of Prodivakaine 5 (vial 20 ml)

Prodivakaine 5 (vial 20 ml) contains methyl hydroxybenzoate (nipagin) which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

3. HOW TO TAKE PRODIVAKAINE 5

Your doctor will inform you about the dose of Prodivakaine 5 you should take, when to take it and the right dose. It is important to follow rigorously the instructions of the doctor and never change the dose by yourself, no matter how you feel.
Check with your doctor or pharmacist if you are not sure about the dose that you should take and when you should take it.

For obstetric anaesthesia a 0.25% and 0.5% solution is recommended. The experiences with obstetric procedures in pregnant women have shown that solution 0.75% should not be used. The dosage of Prodivakaine 5 in local anesthesia varies with the anesthetic procedure, the surface to be anesthetized, the vascularization of the tissues, the number of segments to be blocked, the depth of anesthesia, the required degree of the release of the muscles, the duration of the required anesthesia, individual tolerance and physical condition of the patient. The dose of Prodivakaine 5 should be reduced in the elderly, in debilitated patients, and in cardiac and hepatic disease.

The dosage is as follows:

Peripheral nerve block: the usual dose is 5 ml (25 mg) bupivacaine hydrochloride 0.5% (5 mg/ml).

Surgical anaesthesia

Epidural block

Lumbar: Adults: bupivacaine hydrochloride 5 mg/ml (0.5%), maximum 20 ml.

Caudal: Adults: bupivacaine hydrochloride 5 mg/ml (0.5%), maximum 30 ml.

Major nerve block: bupivacaine hydrochloride 5 mg/ml (0.5%), some ml up to 15 – 20 ml (depends on the type of the nerve).

Obstetric anesthesia:

During labour, for lumbar block: maximum 12 ml of the solution of bupivacaine hydrochloride 5 mg/ml (0.5%).

If you take more Prodivakaine 5 than you should

Serious side effects appear when Prodivakaine 5 is taken more than needed, which can cause even death. The first signs when Prodivakaine is taken more than you should are: lightheadedness, numbness of the tongue and perioral region, numbness of the tongue, eye and ear disorders.

As soon as the doctor notices the first signs mentioned above, he should stop giving Prodivakaine 5.

Other very serious side effects that appear when Prodivakaine 5 is taken more than needed are: tremor, crisis and cardiac problems.

4. POSSIBLE SIDE EFFECTS

Like every drug, Prodivakaine 5 may cause side effects, although not everybody may get them.

Adverse effects apparent after local anaesthesia may be caused by the anaesthetic or errors in technique, or may be the result of blockade of the sympathetic nervous system. Local anaesthetics may produce systemic adverse effects as a result of raised plasma concentrations that occur when the rate of uptake into the circulation exceeds the rate of breakdown.

The systemic toxicity of local anaesthetics mainly involves the CNS and the cardiovascular system. The onset of toxicity can be unpredictable and delayed. The patient should be monitored as per local protocol for at least 30 minutes after administration.

Talk to your doctor if any of the following side effects bothers you:

Side effects are listed below according to their frequency:
Very common: can affect more than 1 in 10 patients.
Common: can affect 1 to 10 patients among 100.
Uncommon: can affect 1 to 10 patients among 1,000.
Rare: can affect 1 to 10 patients among 10,000.
Very rare: can affect less than 1 patient in 10,000.
Not known: frequency cannot be estimated from the available data.

Very common

Hypotension resulting from peripheral vasodilatation (often, hypotension accompanies spinal and epidural anaesthesia; for women in labour, inappropriate positioning of the patient may be a contributory factor), nausea.

Common

Paraesthesia, dizziness, bradycardia, hypertension, vomiting, urinary retention.

Uncommon

Signs of CNS toxicity: convulsions, numbness of the tongue and perioral region, lightheadedness, blurred vision, being sensitive to sounds, tinnitus, loss of consciousness, speech disorders (dysarthria) and tremors.

Rare

Hypersensitivity reactions, arachnoiditis (inflammation of the membrane that surrounds the brain and spinal cord), nerve disorders, paraplegia, cardiac arrest, cardiac arrhythmia, diplopia, respiratory depression.

Not known

Drowsiness, coma.

5. HOW TO STORE PRODIVAKAINE 5

Keep out of the reach and sight of children!

Store in a dry and cool place! Do not store above 25°C!

Keep in the original package to protect it from light!

Do not use the drug after the expiry date which is stated on the packaging.

6. OTHER INFORMATION

What Prodivakaine 5 solution for injection contains

The active substance is bupivacaine hydrochloride.

1 ml solution for injection contains 5 mg bupivacaine hydrochloride.

The excipients are:

Vial 20 ml: sodium chloride, methyl hydroxybenzoate, hydrochloric acid or sodium hydroxide may be added for pH adjustment, water for injection.

Ampoules 2 ml: sodium chloride, hydrochloric acid or sodium hydroxide may be added for pH adjustment, water for injection.

Contents of the pack

Box with one vial of 20 ml.

Box with 10 ampoules of 2 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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