

Approved Patient Information Leaflet

SCHEDULING STATUS

S4

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS solution for injection

Bupivacaine hydrochloride

Sugar free

Read all of this leaflet carefully before you are given BUPIVACAINE HCl 0,5 % (10 ml)

FRESENIUS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is and what it is used for
2. What you need to know before you are given BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS
3. How to receive BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS
4. Possible side effects
5. How to store BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS
6. Contents of the pack and other information.

1. What BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is and what it is used for

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is a local anaesthetic.

It produces loss of feeling or sensation that is confined to one part of the body. BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS belongs to a group of medicines called amide-type anaesthetics.

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is used for surgical operations, e.g., Caesarean section, and for the relief of pain, e.g., labour pain or pain after an operation.

2. What you need to know before you are given BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS should not be given to you:

- if you are hypersensitive (allergic) to bupivacaine hydrochloride or any of the other ingredients of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS (listed in section 6).
- if you are allergic to any other local anaesthetics of the same class (such as lidocaine/lignocaine).
- if you have diseases of the brain or spine such as meningitis or polio.
- if you have a severe headache caused by bleeding inside the head (intracranial haemorrhage).
- if you have problems with your spinal cord due to anaemia.
- if you have brain or spine tumours.
- if you have tuberculosis of the spine.
- if you have a skin infection at or near to where the injection will be given.
- if you have something called cardiogenic shock (a condition where the heart is unable to supply enough blood to the body).
- if you have something called hypovolaemic shock (very low blood pressure leading to collapse).
- if you have problems with blood clotting or are on ongoing treatment for blood clots.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- if you have heart, kidney or liver problems. This is because your doctor may need to adjust the dose of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS.
- if you have a swollen stomach due to more fluid than normal.
- if you have a stomach tumour.
- if you have been told that you have decreased volume of blood (hypovolaemia).
- if you have fluid in your lungs.
- if you have blood poisoning (septicaemia).

If you are not sure if any of the above applies to you, talk to your doctor before you are administered BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS.

Children and adolescents

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS is not recommended for children younger than 12 years.

Other medicines and BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS may interact with certain medicines. In particular, tell your doctor if you are taking any of the following medicines:

- Other local anaesthetics, such as lidocaine (lignocaine).
- Medicines used to treat an uneven heartbeat (antidysrhythmics), such as amiodarone.
- Medicines used to treat high blood pressure, including beta-blockers such as propranolol and calcium channel blockers such as amlodipine.
- Medicines used to treat heartburn or stomach ulcers, such as cimetidine and ranitidine.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before receiving BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS.

Safe use of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS in pregnancy and breastfeeding has not been established.

Driving and using machines:

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS may cause numbness and dizziness and may interfere with your ability to drive or use machinery. Ask your doctor when it would be safe to resume these activities.

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS contains sodium

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS contains 3,15 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,16 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS

You will receive BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS through an injection.

Your doctor will decide how much BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS you should be given depending on the type of surgery and the duration of anaesthesia required.

You will not be expected to give yourself BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS. It will be given to you by a person who is qualified to do so.

If you receive more BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS than you should:

Since a healthcare provider will administer BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS

Since a healthcare provider will administer BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS can have side effects.

Not all side effects reported for BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth, or throat, which may cause difficulty breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellowing of the skin and eyes, also called jaundice,
- chest pain,
- changes in the way your heart beats, for example an unusually slow, fast or irregular heartbeat,

- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- pins and needles,
- dizziness,
- slow heartbeat,
- changes in blood pressure (usually low blood pressure). This might make you feel dizzy or lightheaded,
- high blood pressure,
- feeling sick (nausea) or being sick (vomiting),
- problems passing water.

Less frequent:

- excitement, depression, and nervousness,
- fits (seizures),
- numbness of the tongue or around the mouth,
- ringing in the ears or being sensitive to sound,
- loss of consciousness,
- shaking (tremors),
- light headedness,
- difficulty speaking,
- twitching of your muscles,
- chill or fever,
- drowsiness,

- nerve damage that may cause changes in sensation or muscle weakness (neuropathy).
This may include peripheral nerve damage.
- a condition called arachnoiditis (inflammation of the membrane that surrounds the spinal cord). The signs include a stinging or burning pain in the lower back or legs and tingling, numbness, or weakness in the legs.
- weak or paralysed legs,
- blurred vision, double vision,
- problems with your liver enzymes

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS.

5. How to store BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS

Store at or below 25 °C.

Use immediately after opening.

Discard any unused portion.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS contains

The active substance is bupivacaine hydrochloride.

Each 10 ml of BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS contains 50 mg bupivacaine hydrochloride.

The other ingredients are sodium chloride and water for injection.

What BUPIVACAINE HCl 0,5 % (10 ml) FRESENIUS looks like and contents of the pack:

A clear colourless and odourless solution.

10 ml solution in clear glass ampoules. Pack size of 10 ampoules in an outer cardboard carton.

Holder of Certificate of Registration:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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