

Approved Patient Information Leaflet for Bupivacaine HCl 0,5 % Spinal (4 ml)

Fresenius

SCHEDULING STATUS

S4

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS solution for injection

Bupivacaine hydrochloride

Sugar free.

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

- 1. What BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS is and what it is used for**

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS belongs to a group of medicines called local anaesthetics. It is used at the start of surgery to numb (anaesthetise) the lower part of the body.

2. What you need to know before you are given BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS

BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS (listed in section 6)
- if you are allergic to any other local anaesthetics of the same class (such as lidocaine/lignocaine)
- directly into a vein through a drip (intravenous regional anaesthesia)
- by injection into the vaginal area (paracervical block) during pregnancy or childbirth
- 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 narrowing of the spine or inflammation of the spine (spondylitis)
- if you have tuberculosis of the spine
- if you had a recent spine injury e.g. a broken spine
- if you have blood poisoning (septicaemia)
- 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, liver or lung problems
- if you are of poor general health, elderly or suffer from a temporary illness, or are in the late stages of pregnancy
- if you are a child
- if you suffer from epilepsy (seizures or fits)
- if you have an autoimmune disease called myasthenia gravis
- if you have low blood pressure
- if you have been told that you have decreased volume of blood (hypovolaemia) or are dehydrated
- if you have a swollen belly from too much fluid or from an abnormal growth in your belly.

Children

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS should be given cautiously to children.

Other medicines and BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS

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

Tell your doctor if you are taking any of the following:

- Medicines used to treat heartburn or stomach ulcers, such as cimetidine and ranitidine.
- Other local anaesthetic medicines, such as lidocaine/lignocaine.
- Medicines used to treat an uneven heartbeat (antidysrhythmics), such as mexiletine or amiodarone.

- Medicines used to stop blood clots (anticoagulants).

Pregnancy, breastfeeding and fertility

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 % SPINAL (4 ml) FRESENIUS.

Driving and using machines:

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS may have an effect on mental function and co-ordination and may temporarily impair your movement and alertness.

It is not always possible to predict to what extent BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS affects them.

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS contains sodium

BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS

You will receive BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS through an injection into your spinal cord.

Your doctor will decide how much BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS you should be given depending on your height (this determines the size of your spine), and the level and duration of anaesthesia required.

You will not be expected to give yourself BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS than you should

Since a healthcare provider will administer BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS

Since a healthcare provider will administer BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS can have side effects.

Not all side effects reported for BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting or coma.
- Heart attack.
- Inability to breathe.
- Fits (convulsions).

These are all very serious side effects. If you have them, you may have had a serious reaction to BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Frequent:

- Abnormally slow heart rate.
- Low blood pressure.

Less frequent:

- Difficulty breathing.
- Weak or paralysed legs.
- Muscle weakness and difficulty moving.
- Weakness, numbness and pain in the hands and feet, or a feeling of pins and needles.
- A condition called arachnoiditis (inflammation of the membranes that surround 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.

Frequency unknown:

- Heart problems, including changes in the way your heart beats.
- Infection, abscess or bleeding in the brain or spinal cord.
- Nerve damage that typically results in numbness, tingling, muscle weakness/paralysis and pain in the affected area.
- Numbness of the tongue or mouth.
- Persistent numbness (anaesthesia).
- Blurred vision.
- Ringing in the ears, sensitivity to sound or temporary hearing loss.
- Muscle twitching.
- Shaking (tremors) or shivering.

- Slowing of labour, increased incidence of forceps delivery.
- Intoxication and slow heartbeat in unborn babies when BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESSENIUS is given to pregnant women.

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

Tell your doctor if you notice any of the following:

Frequent:

- Intense headache.
- Feeling sick (nausea).
- Your bladder doesn't empty all the way or at all when you urinate.
- Loss of bladder control.

Less frequent:

- Backache.
- Abnormal, unpleasant or painful sense of touch.
- Being sick (vomiting).

Frequency unknown:

- Light-headedness or dizziness.
- Restlessness.
- Excessive state of heightened energy (excitement).
- Nervousness.
- Drowsiness.
- Headache.
- Eyes sensitive to light.
- Inability to control bowel movements.
- Reduced sexual sensation or sexual function.

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 % SPINAL (4 ml) FRESENIUS.

5. How to store BUPIVACAINE HCl 0,5 % SPINAL (4 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 % SPINAL (4 ml) FRESENIUS contains

The active substance is bupivacaine hydrochloride (anhydrous).

Each 1 ml of BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS contains 5 mg bupivacaine hydrochloride (anhydrous).

The other ingredients are sodium chloride and water for injection.

Sugar free.

What BUPIVACAINE HCl 0,5 % SPINAL (4 ml) FRESENIUS looks like and contents of the pack

A clear colourless and odourless solution.

4 ml solution in 5 ml clear glass ampoules. Pack size of 10 ampoules in an outer cardboard carton.

Holder of Certificate of Registration

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: +27 (0)41 403 1600

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