

Consumer Medicine Information

Bupivacaine spinal heavy BNM

Bupivacaine hydrochloride 20 mg/4 mL (0.5%)

Solution for intrathecal injection

What is in this leaflet

Please read this leaflet carefully before you are given Bupivacaine spinal heavy BNM.

This leaflet answers some common questions about Bupivacaine spinal heavy BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks associated with giving you Bupivacaine spinal heavy BNM against the benefits this medicine is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor, pharmacist or nurse.

Keep this leaflet with the medicine. You may want to read it again.

What Bupivacaine spinal heavy BNM is used for

Bupivacaine spinal heavy BNM contains bupivacaine hydrochloride monohydrate.

Bupivacaine spinal heavy BNM is used to prevent or relieve pain before surgery of the lower abdomen and lower limbs. They will not put you to sleep.

Bupivacaine spinal heavy BNM can also be used to make childbirth less painful.

Bupivacaine spinal heavy BNM belongs to a group of medicines called spinal local anaesthetics. They are injected into the spinal fluid where they make the nerves unable to pass messages to the brain.

Depending on the amount used, Bupivacaine spinal heavy BNM will either totally stop pain or will cause a partial loss of feeling.

Your doctor will have explained why you are being treated with Bupivacaine spinal heavy BNM and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Ask your doctor if you have any questions about why it has been prescribed for you.

Bupivacaine spinal heavy BNM is only available with a doctor's prescription.

Bupivacaine spinal heavy BNM is not addictive.

Before you are given Bupivacaine spinal heavy BNM

When you must not be given it

Bupivacaine is for injection into the spinal canal.

You must not be given Bupivacaine spinal heavy BNM if you are allergic to:

- Bupivacaine hydrochloride.
- other local anaesthetics e.g. lidocaine (lignocaine).
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

You must not be given Bupivacaine spinal heavy BNM if you have any of the following medical conditions:

- problems with your blood pressure or circulation
- blood poisoning
- problems with the clotting of your blood
- nerve or heart problems
- diseases of the brain or spine
- some types of back problems

It may not be safe for you to be given Bupivacaine spinal heavy BNM if you have any of these conditions.



Bupivacaine spinal heavy BNM will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

If you are given Bupivacaine spinal heavy BNM after the expiry date it may have no effect at all, or an entirely unexpected effect.

If you are not sure whether you should be given Bupivacaine spinal heavy BNM, talk to your doctor.

Before you are given it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- problems with your blood pressure or circulation
- blood poisoning
- problems with the clotting of your blood
- nerve or heart problems
- neurological problems including multiple sclerosis and myasthenia gravis
- kidney problems
- malignant hyperthermia
- diseases of the brain or spine including meningitis
- some types of back problems
- low blood pressure

It may not be safe for you to be given Bupivacaine spinal heavy BNM if you have any of these conditions.

Tell your doctor if you are pregnant or intend to become pregnant.

We do not know if it is safe for you to be given it while you are pregnant. It may affect your baby if you take it early in pregnancy or in the last weeks before your baby is due. However, it can be used during childbirth.

Your doctor will discuss the risks and benefits of being given Bupivacaine spinal heavy BNM during pregnancy or childbirth.

Tell your doctor if you are breast-feeding or plan to breastfeed.

Your baby can take in very small amounts of Bupivacaine spinal heavy BNM from breast milk if breastfeeding.

Your doctor will discuss the risks and benefits of being given Bupivacaine spinal heavy BNM when breastfeeding.

If you have not told your doctor or nurse about any of the above, tell them before you are given Bupivacaine spinal heavy BNM.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Bupivacaine spinal heavy BNM may interfere with each other. These include:

- local anaesthetic agents including mexiletine or lidocaine (lignocaine).
- medicines to treat abnormal rhythms of the heart, such as amiodarone.

The above medicines may be affected by Bupivacaine spinal heavy BNM or may affect how well it works. You may need different

amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given Bupivacaine spinal heavy BNM.

How Bupivacaine spinal heavy BNM is given

How it is given

Bupivacaine spinal heavy BNM will be injected by your doctor into the spinal canal through a space between the bones in your lower back. This is called a SPINAL injection and it will result in a feeling of numbness in your lower body, in an area that may seem unrelated to the site of injection.

Bupivacaine spinal heavy BNM must not be injected directly into the blood.

How much will be given

The dose you will be given will depend on your body size, age and the type of pain relief required. Your doctor will determine the best dose for you. They will be willing to discuss this decision with you.

Talk to your doctor if you are not sure about the dose of Bupivacaine spinal heavy BNM you will be given.



While you are being given Bupivacaine spinal heavy BNM

Things to be careful of

Be careful driving or operating machinery after you have been given Bupivacaine spinal heavy BNM.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given Bupivacaine spinal heavy BNM.

If you drink alcohol while you are being given Bupivacaine spinal heavy BNM your blood pressure may drop, making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

In case of overdose

If you are given too much (overdose)

As Bupivacaine spinal heavy BNM is given to you in hospital by your doctor, it is very unlikely that you will receive too much.

Immediately tell your doctor or nurse if you think that you or anyone else has taken or been given too much Bupivacaine spinal heavy BNM.

If you are not in a hospital, immediately telephone your doctor or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and

Emergency at your nearest hospital, if you think that you or anyone else may have been given too much Bupivacaine spinal heavy BNM.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include problems with your sight or hearing, numbness in or around the mouth, dizziness, stiffness, twitchy muscles, convulsions, low blood pressure, and problems with the rhythm of the heart.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or after receiving Bupivacaine spinal heavy BNM.

Like all medicines, Bupivacaine spinal heavy BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- nervousness
- dizziness
- blurred vision
- drowsiness
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea
- vomiting

These are mild side effects.

After a spinal injection you may develop a headache or backache which is not always related to the medicine used. These can, on rare occasions, last for some months after the injection is given.

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

- fits
- unconsciousness
- breathing problems
- low blood pressure
- slow heart beat
- collapse

You may experience these side effects if Bupivacaine spinal heavy BNM is given wrongly, or you are very sensitive to it.

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

Tell your doctor or nurse if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After receiving Bupivacaine spinal heavy BNM

Storage

Bupivacaine spinal heavy BNM should only be given to you in hospital.



It should be stored in a cool dry place where the temperature stays below 25°C.

This is not all the information available on Bupivacaine spinal heavy BNM.

If you have any more questions or are not sure about anything, ask your doctor of pharmacist.

Date of preparation

This leaflet was prepared on 21 April 2020.

Product description

What it looks like

Bupivacaine spinal heavy BNM is a clear colourless sterile solution in a glass ampoule.

It is available as 4 mL glass ampoules in a sterile pack, in a box of 10 ampoules.

Ingredients

Active ingredient:

Bupivacaine hydrochloride monohydrate

Inactive ingredients:

- glucose 8% w/v (80mg/mL)
- sodium hydroxide for pH adjustment
- water for injections.

The solution is preservative free and sulfite free.

Sponsor details

BNM Group
39 Anzac Road
Browns Bay

Auckland 0753

