PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml solution for injection

Bupivacaine hydrochloride

Sugar free

Read all of this leaflet carefully before you are administered PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml

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

What is in this leaflet

1. What PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is and what it is used for

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is a medicine which is used as a local anaesthetic. It produces loss of feeling or sensation that is confined to one part of the body.

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml belongs to a group of medicines called amide-type anaesthetics.

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is used for certain medical or surgical procedures 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 PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is administered to you

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml should not be administered to you:

- If you are hypersensitive (allergic) to bupivacaine hydrochloride or to any of the other ingredients of PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml (listed in section 6).
- If you are hypersensitive (allergic) to any other local anaesthetic medicine of the same class (such as lidocaine [lignocaine]) or ropivacaine.
- 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 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) or hypovolaemic shock (very low blood pressure leading to collapse).

- If you have problems with clotting of your blood or are on ongoing anticoagulation treatment.

Warnings and precautions

Special care should be taken with PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

Your doctor will always keep resuscitation (lifesaving) equipment, oxygen, and medication at hand when any local anaesthetic is used.

This injection may affect your heart more adversely than other local anaesthetic

It may also affect your central nervous system.

These adverse effects may be increased if you have a shortage in the amount of oxygen reaching your tissues or if your body fluids and tissues contain increased levels of acid.

You may experience a decrease in blood pressure after you receive anaesthesia into your spine or into the epidural spaces of your spine.

You may experience a drop in blood pressure while you are in labour and if your body is not in an appropriate position.

Your foetus may be affected following the use of local anaesthetics in labour.

Tell your doctor or health care provider before being given the injection:

- If you are old or weak.
- If you have a muscle disorder causing weakness.
- If you have fits, heart, kidney, and/or liver problems. This is because your doctor may need to adjust the dose of PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml.
- 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).

Children and adolescents

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is not recommended for use in children younger than 12 years.

Other medicines and PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml

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

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml 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 (anti-dysrhythmics), 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 health care provider for advice before receiving PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml.

You will not be given PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml if you are pregnant or breastfeeding since the safety in pregnancy and breastfeeding (other than in labour) has not been established.

It may affect your foetus if used during pregnancy.

The foetal heart rate may slow down abnormally with the use of this injection during labour and your foetus may suffer from excess body acidity.

Added risks occur if your baby is born prematurely, is distressed during labour or if you suffer from pregnancy induced high blood pressure.

Driving and using machines

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml may temporarily impair locomotion and alertness and may cause numbness and dizziness and interfere with your ability to drive or use machinery. Ask your doctor when it would be safe to resume these activities. You should avoid potentially hazardous tasks such as driving and operating machinery until you know how PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml affects you.

3. How PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml will be administered

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml. PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml will be given to you by a person who is qualified to do so in a hospital setting.

You will receive PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml through an injection. Your doctor will choose the dose that is right for you. Your dose will be calculated individually according to certain criteria which your doctor will take into consideration, depending on the type of surgery and the duration of anaesthesia required.

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml will not be given to children younger than 12 years of age.

If you have the impression that the effect of PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml is too strong or too weak, talk to your doctor or pharmacist.

If you receive more PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml than you should

Since a health care provider will administer PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

PHARMA-Q BUPIVACAINE INJECTION50 mg/10 ml overdose:

- If you were given more than you needed, your symptoms will be treated, and supportive measures will be taken (e.g., giving you oxygen).
- If you have severe side-effects to local anaesthetics, steps will be taken to maintain your circulation, breathing and to control any fits that you may experience.
- Therefore, life-saving equipment and medication will always be at hand for any emergencies.
- If you have fits, you will be given oxygen and certain medication directly into your bloodstream.
- If your fits persist, you will be artificially helped with breathing.
- Your circulation will be maintained with fluids given directly into the bloodstream
- You may be given medicines to increase your blood pressure if it drops too low, but you will not be given these medicines during labour.

If you forget to receive PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml

Since a health care provider will administer PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml, it is unlikely that the dose will be missed.

4. Possible side effects

PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml can have side effects.

Not all side effects reported for PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following serious side effects occur, stop receiving PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml 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 in swallowing or breathing,
- rash or itching,
- fainting.

These are serious side effects, and you may have had an allergic reaction to PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml. You may need urgent medical care or hospitalisation.

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

- Dysfunction of the heart, drop in blood pressure and heart rate,
- Abnormal heart rhythms and heart attacks may occur,
- Failure to breathe and coma.

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 with urinating

Less frequent

- Excitation, 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
- Blurred vision, double vision
- 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
- Partial loss of movement (paresis)
- Spinal cord injury (paraplegia)
- Slowed or stopped breathing
- Problems with your liver enzymes (this may happen if you have long-term treatment with this medicine)
- Skin rash or itching
- Skin reaction at the injection site

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions 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 PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml.

5. How to store PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

6. Contents of the pack and other information

What PHARMA-Q BUPIVACAINE INJECTION50 mg/10 ml contains

- The active substance is bupivacaine hydrochloride.

Each 10 ml contains: Bupivacaine hydrochloride monohydrate equivalent to bupivacaine hydrochloride anhydrous 50 mg.

- The other ingredients are sodium hydroxide and water for injections.

What PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml looks like and contents of the pack

A clear, colourless, or almost colourless solution in 10 ml clear colourless glass ampoules.

A clear colourless glass ampoule containing a 0,5 % *m/v* solution of bupivacaine hydrochloride in 10 ml ampoules. Pack size: 10 Ampoules per box.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (Pty) Ltd

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Access to the corresponding Professional Information

TBC