APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Bupivacaine Injection 50 mg/10 ml solution

Read all of this leaflet carefully before you are given 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 or your pharmacist.
- **Pharma-Q Bupivacaine Injection 50 mg/10 ml** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml CONTAINS:

The active substance is bupivacaine hydrochloride.

Each 10 ml contains:

Bupivacaine hydrochloride monohydrate equivalent to bupivacaine hydrochloride anhydrous 50 mg.

Other ingredients are: Sodium hydroxide and Water for injections.

2. WHAT PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml IS USED FOR:

Bupivacaine hydrochloride is a medicine which is used as a local anaesthetic. It is used to block feeling or pain in a certain part of your body. This may be useful in certain medical or surgical procedures.

Date of most recent Council approval: May 2012
Date Compliant with Regulations 9 & 10: 6 March 2015

Your doctor may prescribe **Pharma-Q Bupivacaine Injection 50 mg/10 ml** to block the transmission of pain signals along certain nerves and along certain areas of your spinal cord. This allows you to be pain free in a certain area of your body for a certain period of time and it also allows you not feel any sensation in that area.

3. BEFORE YOU ARE GIVEN PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

You should not be given Pharma-Q Bupivacaine Injection 50 mg/10 ml:

- if you are allergic to bupivacaine hydrochloride or to any other local, anaesthetic agents which are similar in chemical structure to bupivacaine hydrochloride (see **WHAT PHARMA-Q BUPIVACAINE NJECTION 50 mg/10 ml CONTAINS**)
- if you have certain blood deficiencies or if you are receiving certain medicines which may interfere with the local anaesthetic effect of bupivacaine
- if the patients is a child who is under twelve years of age (see **HOW TO RECEIVE PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml**)
- if you need a certain kind of local anaesthetic which has to be injected directly into the vein
- if you need pain relief during giving birth but you need a type of pain block called paracervical block as it may slow the foetal heart rate (see **Pregnancy and Breastfeeding**)
- if you have any inflammation of the lining of the brain or spinal cord or if you have any blood clotting problems
- if you are pregnant or breastfeeding (other than in labour) as the safety in pregnancy and lactation has not been established (see **Pregnancy and Breastfeeding**).

Tell your doctor or healthcare professional before being given the injection.

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Special care should be taken with Pharma-Q Bupivacaine Injection 50 mg/10 ml:

- Your doctor will always keep resuscitation (life-saving) equipment, oxygen and medication at hand when any local anaesthetic is used (see **HOW TO RECEIVE PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml and OVERDOSE** sections)
- 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.

Also take special care with Pharma-Q Bupivacaine Injection 50 mg/10 ml:

- You may experience a decrease in blood pressure after you receive anesthesia 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
- You will be given local anaesthetics with caution if you are old or weak (see **HOW TO RECEIVE PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml**) or if you have fits, heart problems and/or liver damage
- You may be more at risk to the adverse effects of local anaesthetics if you have a muscle disorder causing weakness.

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Pregnancy and Breastfeeding:

You will not be given **Pharma-Q Bupivacaine Injection 50 mg/10 m** if you are pregnant or breastfeeding since the safety in pregnancy and breastfeeding (other than in labour) has not been established (see **You should not be given Pharma-Q Bupivacaine Injection 50 mg/10 ml**)

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 (see **You should not be given Pharma-Q Bupivacaine Injection 50 mg/10 ml**) 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.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before you receive **Pharma-Q Bupivacaine Injection 50 mg/10 ml.**

Driving and using machinery:

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.

Taking other medicines with Pharma-Q Bupivacaine Injection 50 mg/10 ml:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

4. HOW TO RECEIVE PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

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

Always receive **Pharma-Q Bupivacaine Injection 50 mg/10 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Bupivacaine Injection 50 mg/10 ml will be given to you by a doctor or nurse in a hospital setting. 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

Pharma-Q Bupivacaine Injection 50 mg/10 ml will not be given to children younger than 12 years of age (see **You will not be given Pharma-Q Bupivacaine Injection 50 mg/10 ml**)

Your dose will not be exceeded unless your doctor feels that you have special considerations present.

Your dosage will be calculated with caution if you are old or weak (see **Also take special care**).

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 are given more Pharma-Q Bupivacaine Injection 50 mg/10 ml than you should:

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. If you think you have been given too much, you must tell the person giving you the injection.

Pharma-Q Bupivacaine Injection 50 mg/10 ml overdose:

For symptoms see **POSSIBLE SIDE EFFECTS** and **Special care should be taken with Pharma-Q Bupivacaine Injection 50 mg/10 ml**:

- 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 (see **Take Special Care**)

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- 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.

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of Pharma-Q Bupivacaine Injection 50 mg/10 ml:

If you think that you did not receive a dose of **Pharma-Q Bupivacaine Injection 50 mg/10 ml**, contact your doctor.

If you have any further questions on the use of **Pharma-Q Bupivacaine Injection 50 mg/10 ml**, ask your doctor, nurse, or pharmacist.

5. 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:)

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

These 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 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 as soon as possible if you notice any of the following:

- restlessness, excitement, nervousness, dizziness, drowsiness
- ringing in the ear, blurred vision
- nausea and vomiting, muscle twitching, tremors, and fits
- Numbness of the tongue and around the mouth region.

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

6. STORING AND DISPOSING OF PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

Store at or below 25 °C.

Keep out of reach of children.

Protect from light.

7. PRESENTATION OF PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

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

8. IDENTIFICATION OF PHARMA-Q BUPIVACAINE INJECTION 50 mg/10 ml:

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

9. REGISTRATION NUMBER:

31/4/0007

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa

11. DATE OF PUBLICATION:

Original date of registration: 27 February 1997

Revised package insert approval: May 2012

Date of most recent Council approval: May 2012
Date Compliant with Regulations 9 & 10: 6 March 2015