PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Bupivacaine Spinal with Dextrose Injection (20 mg/4 ml) solution

Read all of this leaflet carefully before you are given Pharma-Q Bupivacaine Spinal with Dextrose Injection

- 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 Spinal with Dextrose Injection** 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 SPINAL WITH DEXTROSE INJECTION CONTAINS:

The active substance is bupivacaine hydrochloride.

Each 4 ml in 5 ml ampoule contains:

- A hyperbaric solution containing bupivacaine hydrochloride monohydrate equivalent to bupivacaine hydrochloride anhydrous 20 mg.
- Dextrose anhydrous 290,8 mg (as dextrose monohydrate 320 mg).

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

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

2. WHAT PHARMA-Q BUPIVACAINE SPINAL WITH DEXTROSE INJECTION 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.

Your doctor may prescribe **Pharma-Q Bupivacaine Spinal with Dextrose Injection** 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.

Your doctor will prescribe this injection if you are undergoing any:

- operations of the urinary tract (male or female)
- operations of the male reproductive organs
- operations of the lower limbs of the body
- operation which involves any organs in the abdominal area.

3. BEFORE YOU ARE GIVEN PHARMA-Q BUPIVACAINE SPINAL WITH DEXTROSE INJECTION:

You should not be given Pharma-Q Bupivacaine Spinal with Dextrose Injection:

- 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 SPINAL WITH DEXTROSE INJECTION CONTAINS**)

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

- 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 SPINAL WITH DEXTROSE INJECTION**)
- 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:

Special care should be taken with Pharma-Q Bupivacaine Spinal with Dextrose Injection:

- 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 SPINAL WITH DEXTROSE INJECTION and OVERDOSE** sections)
- this injection may affect your heart more adversely than other local anaesthetic
- it may also affect your central nervous system

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

- 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 Spinal with Dextrose Injection:

- 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
- you will be given local anaesthetics with caution if you are old or weak (see **HOW TO RECEIVE PHARMA-Q BUPIVACAINE SPINAL WITH DEXTROSE INJECTION**) 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.

Special care taken with spinal anaesthetics:

- it will be used with caution if you have any heart or circulatory problems
- your vital signs and state of consciousness will be constantly monitored after you receive this injection
- your dose will be calculated very cautiously in order to avoid dose-related adverse effects like fits and collapse of the heart or circulatory system
- you may experience certain adverse effects to the nerves following spinal anaesthesia. These include:

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

- impaired sensation in the perineal area (region between the anus and genital areas) and decreased sexual function
- persistent loss of sensation, pins and needles, weakness and loss of movement in the lower extremities
- abnormal holding of urine
- involuntary bowel or bladder movements
- low blood pressure
- high or total spinal block, headache, backache, inflammation or irritation of the lining of the brain
- slowing of labour and increased incidence of forceps delivery
- shivering and increased pressure on nerves in the brain
- spinal headache (due to leakage of spinal fluid).

Pregnancy and Breastfeeding:

You will not be given **Pharma-Q Bupivacaine Spinal with Dextrose Injection** 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 Spinal with Dextrose Injection**)

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 Spinal with Dextrose Injection**) and your foetus may suffer from excess body acidity (this occurs when the injection is given to cause a certain block called a paracervical block).

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 Spinal with Dextrose Injection.**

Driving and using machinery:

You should avoid potentially hazardous tasks such as driving and operating machinery until you know how **Pharma-Q Bupivacaine Spinal with Dextrose Injection** affects you.

Taking other medicines with Pharma-Q Bupivacaine Spinal with Dextrose Injection:

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 SPINAL WITH DEXTROSE INJECTION:

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

Always receive **Pharma-Q Bupivacaine Spinal with Dextrose Injection** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Bupivacaine Spinal with Dextrose Injection 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.

Pharma-Q Bupivacaine Spinal with Dextrose Injection:

- your dose will be individually calculated according to certain criteria which your doctor will take into consideration and according to the type of surgery that you are undergoing
- your doctor will also take into consideration the position in which you will be laying in during surgery, as this may affect how this medicine works

- your doctor will always have life-saving equipment, oxygen and medicine available, should you have any severe adverse reactions like heart or circulatory collapse (see **Take special care**)
- this medicine will not be given to children younger than 12 years of age (see **You will not be given Pharma-Q Bupivacaine Spinal With Dextrose Injection**)
- 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 Spinal with Dextrose Injection** is too strong or too weak, talk to your doctor or pharmacist.

If you are given more Pharma-Q Bupivacaine Spinal with Dextrose Injection 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 Spinal with Dextrose Injection overdose:

For symptoms see **POSSIBLE SIDE EFFECTS** and **Special care should be taken with Pharma-Q Bupivacaine Spinal with Dextrose Injection**.

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

Pharma-Q Bupivacaine Spinal with Dextrose Injection:

- 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**)
- 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 Spinal with Dextrose Injection:

If you think that you did not receive a dose of **Pharma-Q Bupivacaine Spinal with Dextrose Injection**, contact your doctor.

If you have any further questions on the use of **Pharma-Q Bupivacaine Spinal with Dextrose Injection**, ask your doctor, nurse, or pharmacist.

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

5. POSSIBLE SIDE EFFECTS:

Pharma-Q Bupivacaine Spinal with Dextrose Injection can have side effects.

Not all side effects reported for **Pharma-Q Bupivacaine Spinal with Dextrose Injection** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Bupivacaine Spinal with Dextrose Injection**, 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 Spinal with Dextrose Injection 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.

These serious side effects and you may have had an allergic reaction to **Pharma-Q Bupivacaine Spinal with Dextrose Injection.** 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

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

- 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 SPINAL WITH DEXTROSE INJECTION:

Store at or below 25 °C.

Keep out of reach of children.

Protect from light.

7. PRESENTATION OF PHARMA-Q BUPIVACAINE SPINAL WITH DEXTROSE INJECTION:

A hyperbaric 0,5 % solution of bupivacaine hydrochloride. Packs of 10 x 4 ml in 3 ml clear, colourless, type I glass ampoules.

8. IDENTIFICATION OF PHARMA-Q BUPIVACAINE SPINAL WITH DEXTROSE INJECTION:

A clear colourless to light yellow solution in 5 ml clear, colourless, type I ampoules containing 4 ml injection.

9. REGISTRATION NUMBER:

31/4/0006

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015

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: 6 March 1997

Revised package insert approval: June 2015

Date of most recent Council approval: June 2012
Date Compliant with PIL Guidelines: 6 March 2015