PATIENT INFORMATION LEAFLET

1. SCHEDULING STATUS:

S6

2. PROPRIETARY NAME, STRENGTH PHARMACEUTICAL FORM :

Pharma-Q Pethidine Injection 25 mg/1 ml solution for injection

Pharma-Q Pethidine Injection 50 mg/1 ml solution for injection

Pharma-Q Pethidine Injection 100 mg/2 ml solution for injection

Read all of this leaflet carefully before you start taking Pharma-Q Pethidine Injection

- Keep this leaflet. You may need to read it again.
- It contains information on **Pharma-Q Pethidine Injection** which is part of your hospital treatment.
- If you have further questions, please ask your doctor or your nurse who will be administering this medicine.
- **Pharma-Q Pethidine 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.

3. WHAT PHARMA-Q PETHIDINE INJECTION CONTAINS:

The active substance is pethidine hydrochloride.

- 1 ml Ampoules containing 25 mg pethidine hydrochloride
- 1 ml Ampoules containing 50 mg pethidine hydrochloride
- 2 ml Ampoules containing 100 mg pethidine hydrochloride

The other ingredients are: hydrochloric acid, water for injections.

4. WHAT PHARMA-Q PETHIDINE INJECTION IS USED FOR:

Pharma-Q Pethidine Injection contains pethidine hydrochloride and it is prescribed by your doctor:

- To give you relief from severe pain
- To give you relief of post-operative pain
- To give you relief from labour pain
- As pre-medication for you before your operation.

5. BEFORE YOU RECEIVE PHARMA-Q PETHIDINE INJECTION:

You will not be given Pharma-Q Pethidine Injection:

- If you are sensitive or have an allergy to pethidine hydrochloride or any of the other ingredients in this injection (see **WHAT PHARMA-Q PETHIDINE INJECTION CONTAINS**)
- If you suffer from respiratory depression (troubled breathing for e.g. asthma or bronchitis), especially in the presence of cyanosis (blue colour of tissues caused by too little oxygen) and excessive bronchial secretion, chronic lung disease, kidney and liver insufficiency
- If you suffer from alcoholism, head injuries, and conditions in which intracranial pressure is raised (pressure inside the skull)
- If you are being monoamine oxidase inhibitors (medicines used to treat depression), or within 2 weeks of the discontinuation of such treatment (see **Interactions**)
- If you are suffering from an attack of bronchial asthma or you are in heart failure secondary to chronic lung disease
- If you are in a coma
- If you are pregnant or breast-feeding as safety has not been established (see **Pregnancy and Breastfeeding**).

Take special care with Pharma-Q Pethidine Injection:

If you are given **Pharma-Q Pethidine Injection** for a prolonged period of time its use may lead to dependence.

Pharma-Q Pethidine Injection will be administered with **caution:**

- If you suffer from supraventricular tachycardia (increased rate of heartbeat) or have a history of convulsive disorder (fits)
- If you suffer from phaeochromocytoma (tumour of the adrenal gland) as it may provoke episodes of hypertension
- In infants, more especially neonates since it may cause breathing problems in the neonate.

Pharma-Q Pethidine Injection will be administered with **caution or in reduced doses** if you suffer from:

- Hypothyroidism (underactive thyroid gland)
- Adrenocortical insufficiency (underactive adrenal glands)
- Asthma
- Decreased respiratory reserve
- Impaired kidney or liver function
- Prostatic hyperplasia (enlarged prostate gland)
- Hypotension (low blood pressure)
- Shock
- Inflammatory or obstructive bowel disorders
- Myasthenia gravis (muscle disorder causing weakness).

Pharma-Q Pethidine Injection:

- Your dosage will be reduced if you are old and debilitated
- Your depressant effects will be enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics (medicines to induce sleep) and sedatives (medicines to relax you), tricyclic antidepressants (medicines for depression), and phenothiazines (medicines used for mental illness or for nausea or vomiting)

- You may develop hypotension if you use it in conjunction with meprobamate and phenothiazines
- You may suffer from hypotension and vasodilation with intravenous injection
- You will be monitored if you receive any intra-spinal narcotics
- May prolong labour and cause respiratory depression in the newborn.
- Is regarded as a medicine of addiction.

Ability to drive or operate machinery:

Pharma-Q Pethidine Injection may cause drowsiness that may affect the ability to perform skilled tasks. If you experience such effects after you receive your injection you will be advised not drive or operate machinery.

Pregnancy and Breastfeeding:

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 Pethidine Injection**

You will not be given **Pharma-Q Pethidine Injection** if you are pregnant or breast feeding as safety in pregnancy and lactation has not been established (see **You will not be given Pharma-Q Pethidine Injection**).

Pharma-Q Pethidine Injection:

- The administration during labour may cause respiratory depression (breathing problems) in the newborn infant
- Respiratory depression varies according to the timing and size of the dose given to the mother
- Foetal depression is not apparent immediately when delivery occurs and may occur 1-3 hours after delivery
- Crosses the placenta and is excreted in breast milk.

Taking other medicines with Pharma-Q Pethidine Injection:

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

(This includes complementary or traditional medicines.)

Pharma-Q Pethidine Injection may interact with:

- **MAOI (mono-amine oxidase inhibitors):**

  Pharma-Q Pethidine Injection will not be given to you if you are receiving MAOI (medicine used to treat depression) or within 14 days after you have stopped the medication as very severe reactions, including coma, respiratory depression (breathing problems), cyanosis (blue colour in tissues due to decreased oxygen) and low blood pressure may occur. MAOI enhances the effects of **Pharma-Q Pethidine Injection**.

- **Barbiturates and other opioid analgesics:**

  Opioid analgesics and barbiturates can increase central nervous system (CNS) depressant effects when used concomitantly with alcohol, anaesthetics, anxiolytics (medicines to treat anxiety), hypnotics (sleeping tablets), tricyclic anti-depressants (medicines to treat depression) and anti-psychotics (medicines to treat mood disorders).

- **Histamine H_2antogonists:**

  Cimetidine (for heartburn or ulcer) reduces the clearance and distribution of **Pharma-Q Pethidine Injection** from your bloodstream.

- **Phenothiazines:**

  Prochlorperazine (medicines to control mental illness or nausea and vomiting) prolongs the respiratory depressant effect of **Pharma-Q Pethidine Injection**.

6. HOW YOU WILL BE GIVEN PHARMA-Q PETHIDINE INJECTION:

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

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

Pharma-Q Pethidine Injection will be given to you by a doctor or nurse in hospital. Your doctor will choose the dose that is right for you.

Pharma-Q Pethidine Injection may be given by injection into:

- A muscle (intramuscular)
- The tissue just beneath the skin (subcutaneous)
- Slow injection into a vein (intravenous).

Pharma-Q Pethidine Injection dosages:

- **Children:**

  Intramuscular injection:

  0,5 mg to 2 mg per kg body-mass, but will not exceed the adult dose.

- **Adults:**

  Subcutaneous or Intramuscular injection:

  25 mg to 100 mg.

- **Slow intravenous injection:**

  In doses of 25 mg to 50 mg.

Other uses:

Obstetric Analgesia (pain relief during childbirth):

Intramuscular or subcutaneous injection:

50 mg to 100 mg may be given to you as soon as contractions occur at regular intervals. Your dose may be repeated after 1 to 3 hours if necessary.

Epidural administration (pain relief by injection into the epidural spaces of the spine):

Slow injection:

- **Pharma-Q Pethidine Injection** will be administered by slow injection into the epidural spaces
- With epidural administration, caution will be exercised in the presence of respiratory depression (abnormally slow or shallow breathing) and in the presence of foetal distress
- Epidural administration requires that you should be in a high care environment with continuous supervision
- You will be closely monitored for at least 2 hours after each dose, as early respiratory depression may occur.

In addition to conventional routes of administration **Pharma-Q Pethidine Injection** may be given epidurally and intrathecally.

Intraspinal doses are in the region of 20 mg to 150 mg for initial epidural injection or at an infusion rate of 5 mg to 20 mg per hour. Onset of action is around 5 minutes. The duration of effect of a single dose is 4 to 8 hours.

If you have the impression that the effect of **Pharma-Q Pethidine Injection** is too strong or too weak, talk to your doctor or pharmacist.

If you missed a dose of Pharma-Q Pethidine Injection:

If you think that you did not receive a dose of **Pharma-Q Pethidine Injection** contact your doctor.

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

If you receive more Pharma-Q Pethidine Injection than you should:

If you think that too much of this injection was given to you, tell your doctor immediately.

Overdose with **Pharma-Q Pethidine Injection** may cause:

- Muscular twitching
- Tremors
- Hyperactive reflexes
- Dilated pupils and convulsions followed by respiratory depression (abnormally slow or shallow breathing)
- Hypotension (low blood pressure) with circulatory failure and deepening coma
- Death may occur from respiratory failure
- Rhabdomyolysis (abnormal muscle breakdown which can lead to kidney problems) progressing to renal failure may occur.

Treatment of toxic effects:

- Your stomach will be emptied by aspiration and lavage if an oral overdose occurs
- You will be given intensive supportive therapy to correct respiratory failure and shock
- You will be given a specific antagonist (naloxone hydrochloride) to counteract very rapidly the severe breathing problem and coma produced by overdose
- Your doctor will prescribe the correct dosage which will be given in to a vein
- Naloxone may also be given by in the tissue just beneath the skin or injected into a muscle
- Additional doses may be required to prevent relapses. Respiration assistance may be necessary and your circulation maintained with dextrose and suitable electrolyte solutions

- Further treatment will be to treat your symptoms.

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

7. POSSIBLE SIDE EFFECTS:

Pharma-Q Pethidine Injection can have side effects.

Side-effects:

Nervous system disorders:

Frequency unknown: Dysphoria (depressed mood), confusion, drowsiness, dizziness, raised intracranial pressure, headache, vertigo, restlessness, changes in mood and hallucinations.

Eye disorders:

Frequency unknown: Miosis (contraction of the pupil of the eye) may occur more frequently in ambulant patients (mobile) than in those at rest in bed.

Cardiovascular disorders:

Frequency unknown: Intravenous injection may produce vasodilation (broadening of blood vessels) and hypotension (low blood pressure), bradycardia (slow heart rate), tachycardia (increased heart beat), palpitations (rapid, irregular beat) and orthostatic hypotension (low blood pressure when standing up).

Gastrointestinal disorders:

Frequency unknown: Nausea, vomiting, constipation and dry mouth.

Hepatobiliary disorders:

Frequency unknown: Biliary spasm (spasm of bile duct).

Skin and subcutaneous tissue disorders:

Frequency unknown: Sweating, facial flushing, hypothermia (low body temperature) and anaphylactic reactions following IV administration.

Frequency unknown*:* Due to histamine releasing effect, reactions such as urticaria and pruritus.

Musculoskeletal, connective tissue and bone disorders:

Frequency unknown: Muscle rigidity (stiffness) following high doses

Renal and urinary disorders:

Frequency unknown: Urinary retention (anti-diuretic effect), difficulty in micturition, uretic or biliary spasm.

Reproductive system and breast disorders:

Frequency unknown: Decreased libido (decreased sexual desire) or potency.

General disorders and administrative site disorders:

Frequency unknown: Local reactions often follow injections of pethidine and general hypersensitivity reactions.

Larger doses of **Pharma-Q Pethidine Injection** may produce:

- Respiratory depression (abnormally slow or shallow breathing) and hypotension (low blood pressure), with circulatory failure and deepening coma
- Convulsions (fits) may occur in infants and children
- Death may occur from respiratory failure
- Not all side effects reported for **Pharma-Q Pethidine Injection** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving

Pharma-Q Pethidine Injection, please consult your doctor, pharmacist or other health care professional for advice.

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

8. STORING AND DISPOSING OF PHARMA-Q PETHIDINE INJECTION:

Do not use this product after the expiry date printed on the ampoule and carton.

Store at or below 25 °C.

Protect from light.

Store all medicines out of reach of children.

9. PRESENTATION OF PHARMA-Q PETHIDINE INJECTION

Pharma-Q Pethidine Injection 25 mg/1 ml: Containers of 10 or 100 x 1 ml ampoules

Pharma-Q Pethidine Injection 50 mg/1 ml: Containers of 10 or 100 x 1 ml ampoules

Pharma-Q Pethidine Injection 100 mg/2 ml: Containers of 10 or 100 x 2 ml ampoules

10. IDENTIFICATION OF PHARMA-Q PETHIDINE INJECTION

Clear, colourless solution in clear, colourless glass ampoules.

11. REGISTRATION NUMBERS:

Pharma-Q Pethidine Injection 25 mg/1 ml: 31/2.9/0083

Pharma-Q Pethidine Injection 50 mg/1 ml: 31/2.9/0084

Pharma-Q Pethidine Injection 100 mg/2 ml: 31/2.9/0085

12. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

13. DATE OF PUBLICATION:

Original date of registration: November 2010

Revised package insert approval: June 2015