Patient Information Leaflet

1. SCHEDULING STATUS:

S6

2. PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Morphine Injection 10 mg solution for injection

Pharma-Q Morphine Injection 15 mg solution for injection

3. Read all of this leaflet carefully before you start receiving Pharma-Q Morphine Injection.

- Keep this leaflet. You may need to read it again.
- It contains information on **Pharma-Q Morphine 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 Morphine 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 MORPHINE INJECTION CONTAINS:

The active substance is: morphine sulphate.

Each 1 ml ampoule contains 10 mg or 15 mg morphine sulphate, without preservative.

The other ingredients are: nitrogen, sodium chloride, water for injections.

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

Pharma-Q Morphine Injection belongs to a group of medicines known as **painkillers** (opiate analgesics).

Your doctor has prescribed Pharma-Q Morphine Injection for you in order to relieve severe or very

severe pain which you may be experiencing.

5. BEFORE YOU ARE GIVEN PHARMA-Q MORPHINE INJECTION:

You will NOT be given Pharma-Q Morphine Injection:

- If you are sensitive or allergic to Morphine Sulphate or any of the other ingredients in this injection (see **WHAT PHARMA-Q MORPHINE INJECTION CONTAINS**)
- If you suffer from a breathing disorder
- If you have sustained a head injury or raised pressure around your brain
- If you suffer from a convulsive disorder (epilepsy) or suffer from fits (seizures)
- If you suffer from acute alcohol poisoning (intoxication)
- If you are suffering from an attack of bronchial asthma
- If you suffer from low blood pressure with a lack of adequate circulatory filling or lung disorders
- If you suffer from a narrowing of the tubes leading to your bladder
- If you are pregnant or breast feeding unless the benefits outweigh the risk
- If you are unconscious (coma).

Please tell your doctor or nurse before being given the injection if you suffer from:

- Low blood pressure
- An under-active thyroid gland
- Asthma or other breathing difficulties
- Kidney or liver disorders.

Children:

- Pharma-Q Morphine Injection will not usually be given before an operation to children under 1 year of age, and it will be given with extreme care to newborn or premature infants for other conditions.
- If you have any concerns ask your doctor or pharmacist.

Alcohol:

Alcohol should be avoided during treatment.

Take special care with Pharma-Q Morphine Injection:

The euphoric (unrealistic feeling of well being) activity of morphine sulphate may lead to abuse, hence dependence and tolerance to morphine may occur.

Pharma-Q Morphine Injection (opioid analgesic):

- Will be used with extreme caution if you suffer from a respiratory problem as its use may lead to respiratory depression
- It will be administered with caution and in reduced doses if you suffer from:
    - Hypothyroidism (decreased thyroid function)
    - Adrenocortical insufficiency (disorders of the adrenal gland)
    - Impaired kidney or liver function
    - Prostatic hypertrophy (enlargement) or shock
    - Inflammatory or obstructive bowel disorders.
- It will be administered with caution:
    - If you suffer from myasthenia gravis (muscle disorder causing weakness)
    - If you are taking monoamine oxidase inhibitors (see **Interactions**).
- If you are taking central nervous system depressants such as alcohol, anaesthetics, hypnotics and sedatives, tricyclic anti-depressants and phenothiazines, the depressant effects of Pharma-Q Morphine Injection may enhanced (see **Taking other medicines with**

Pharma-Q Morphine Injection)

- If you are old or debilitated your dosage will be reduced (see **Dosage and Directions**)
- If you are given Pharma-Q Morphine Injection during labour, it may cause respiratory depression in the newborn infant (see **Pregnancy and Lactation**)
- I you suffer from the triad of coma, pinpoint pupils and respiratory depression, it is considered indicative of overdosage. Dilatation of the pupils occurs as hypoxia (decreased oxygen in the tissues) develops. Pulmonary oedema (fluid in the lungs) after overdosage is a common cause of fatalities among opioid addicts.

Ability to drive and use machinery:

You may suffer from drowsiness which may affect your ability to perform skilled tasks. If you experience such effects you will be advised by your healthcare practitioner not drive or operate machinery.

Pregnancy or breast feeding:

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 Morphine Injection.
You will not be given Pharma-Q Morphine Injection during pregnancy and lactation (unless the benefits outweigh the risk) since the safety and efficacy of Pharma-Q Morphine Injection has not been established (see **You will not be given Pharma-Q Morphine Injection)**

Morphine Sulphate:

- Has the potential of crossing the placenta and also of being distributed into the breast-milk
- Regular use during pregnancy may cause physical dependence in the foetus, leading to withdrawal symptoms in the neonate
- Use during labour may cause respiratory depression in the neonate (see **Take special care with Pharma-Q Morphine Injection**)

Taking other medicines with Pharma-Q Morphine Injection:

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

(This includes complementary or traditional medicines.)

This is especially important with the following medicines as they may interact with Pharma-Q Morphine Injection:

- Central nervous system depressants such as alcohol, anaesthetics, hypnotics and sedatives
- Tricyclic antidepressants
- Mono-amine oxidase inhibitors (medicines used for depression)
- Phenothiazines
- Other painkillers (especially pentazocine, nalbuphine or buprenorphine)
- Muscle relaxants
- Diuretics (water tablets that increase urine excretion)
- Cimetidine (an anti-ulcer treatment)
- Anti-arrhythmics medicines to control heart rhythm or rate (e.g. mexiletine)
- Medicines used to treat anxiety
- Medicines to help you sleep
- Medicines for treatment of digestive tract disorders (e.g. cisapride)
- Medicines used for Parkinson's Disease
- Medicines used to treat vomiting or indigestion (e.g. domperidone or metoclopramide).

6. HOW TO RECEIVE PHARMA-Q MORPHINE INJECTION:

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

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

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

The usual dose will be administered by subcutaneous (under the skin) or intramuscular (into a muscle) injection:

- **Adults:** 5 to 20 mg every 4 hours
- **Children:** 1 to 5 years - 2,5 to 5 mg
  6 to 12 years - 5 to 10 mg.

- Your doctor will decide on the correct dosage and how and when the injection will be given
- The injection can also be administered into the vein, spine or spaces in between the spine
- Your doctor or nurse may adjust the dose of your medicine and the number of injections you are given each day until your pain is relieved
- Doses will generally be reduced if you are old or debilitated or if you suffer from renal impairment.

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

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

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

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

Do not share medicines prescribed for you with others

If you receive more of Pharma-Q Morphine 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.

Tell your doctor or nurse immediately if any of the following symptoms of overdose occur:

- Cold, clammy skin
- Confusion
- Convulsion
- Severe dizziness
- Severe drowsiness
- Low blood pressure
- Severe nervousness or restlessness
- Pinpoint pupils of eyes
- Slow heartbeat
- Slow or troubled breathing
- Unconsciousness
- Weakness

Medical therapy:

- Intensive supportive therapy may be required to correct respiratory failure and shock
- In addition, the specific antagonist naloxone hydrochloride will be used by your doctor to counteract very rapidly the severe respiratory depression and coma produced by excessive doses of opioid analgesics
- Naloxone may also be given by subcutaneous or intramuscular injection
- The effect of naloxone may be of shorter duration than that of the opioid analgesic and additional doses may be required to prevent relapses
- Pharma-Q Morphine Injection may cause dependence with long-term use
- If your treatment is stopped too quickly then withdrawal symptoms may occur

- Please tell your doctor or nurse if you think this is happening to you
- However, when the dose of Pharma-Q Morphine Injection is carefully adjusted to control pain, dependence and other side effects occur less frequently.

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

7. POSSIBLE SIDE EFFECTS:

Pharma-Q Morphine Injection can have side effects.

Neurological disorders:

Frequent: **Normal doses:** Drowsiness and dizziness.

Less frequent: **Normal doses:** Restlessness, confusion, headache and hallucinations (a perception of seeing or hearing things).

Larger doses: Respiratory depression (shallow breathing).

Frequency unknown:

Normal doses: Vertigo (light headedness), raised intracranial pressure and the euphoric (unnatural feeling of well being) activity of morphine leads to abuse and dependence.

Larger doses: Convulsions may occur, especially in infants and children.

Disorders of the eye:

Frequency unknown:

Normal doses: Miosis (contraction of the pupil).

Cardiovascular disorders:

Frequent: **Normal doses:** Orthostatic hypotension (drop in blood pressure when standing up).

Less frequent: **Normal doses:** Bradycardia (abnormally slow pulse rate), tachycardia (increased rate of heartbeat) and palpitations (rapid irregular action of heart).

Frequency unknown:

Larger doses: Hypotension (low blood pressure) with circulatory failure and deepening coma as well as death from respiratory failure.

Gastrointestinal disorders:

Frequent: **Normal doses:** Nausea, vomiting, constipation.

Less frequent*:* **Normal doses:** Biliary spasm and dry mouth.

Frequency unknown:

Normal doses: Anorexia (loss of appetite).

Skin and subcutaneous tissue disorders:

Frequent: Histamine release causing urticaria (rash), pruritus (itching) and contact dermatitis.

Less frequent: Pain and irritation may occur at the site of injection.

Histamine release:

- Due to the histamine-releasing effect, urticarial, pruritus and contact dermatitis as well as hypotension and flushing may occur
- Anaphylactic reactions (life-threatening allergic reactions) following intravenous injection may occur as well as muscle rigidity
- Tell your doctor or nurse immediately if you get any sudden difficulties in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body)
- Toxic doses vary considerably with the individual and regular users may tolerate large doses

Renal and urinary disorders:

Less frequent: **Normal doses:** Ureteric spasm as well as an anti-diuretic effect may occur (problems with urination).

Frequency unknown:

Normal doses: Micturition may be difficult.

Larger doses: Rhabdomyolysis progressing (abnormal muscle breakdown causing kidney problems) to renal failure may occur with overdosage.

Disorders of the reproductive system and breast:

Frequency unknown:

Normal doses: Decreased libido (sexual desire) or potency.

General disorders:

Frequency unknown:

Normal doses: Sweating, facial flushing, hypothermia (low body temperature), changes of mood.

Not all side effects reported for Pharma-Q Morphine Injection are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Pharma-Q Morphine 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 MORPHINE INJECTION:

Store at or below 25 °C.

Protect from light.

Keep out of reach of children.

9. PRESENTATION OF PHARMA-Q MORPHINE INJECTION:

1 ml amber ampoules in containers of 10 or 100

10. IDENTIFICATION OF PHARMA-Q MORPHINE INJECTION:

A sealed amber ampoule containing a clear colourless to slightly yellow solution.

11. REGISTRATION NUMBER:

Pharma-Q Morphine Injection 10 mg: 29/2.7/0475

Pharma-Q Morphine Injection 15 mg: 29/2.7/0476

12. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

13. DATE OF PUBLICATION:

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