

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S6****Pharma-Q Morphine Injection 10 mg solution for injection****Pharma-Q Morphine Injection 15 mg solution for injection****Morphine Sulphate****Sugar free****Read all of this leaflet carefully before you are given Pharma-Q Morphine Injection**

- 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.
- 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.

What is in this leaflet

1. What Pharma-Q Morphine Injection is and what it is used for
2. What you need to know before you are given Pharma-Q Morphine Injection
3. How Pharma-Q Morphine Injection will be given to you
4. Possible side effects
5. How to store Pharma-Q Morphine Injection
6. Contents of the pack and other information

1. What Pharma-Q Morphine Injection is and what it is used for

The active substance is morphine sulphate.

Morphine 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 and persistent pain which you may be experiencing, where non-narcotic pain relief medication is ineffective.

2. What you need to know before you are given Pharma-Q Morphine Injection

Pharma-Q Morphine Injection should not be given to you:

- If you are hypersensitive (allergic) to morphine sulphate or any of the other ingredients of Pharma-Q Morphine Injection listed in section 6.
- If you have difficulty in breathing, shortness of breath, suffer from chronic asthma, chronic lung disease and any obstructive airway disease.
- If you have excessive bronchial secretion.
- 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) or alcoholism.
- If you suffer from heart problems
- If you suffer from a narrowing of the tubes leading to your bladder or have severe stomach cramps caused by a condition known as biliary colic.
- If you have been told you have a tumour of the adrenal gland near your kidney called phaeochromocytoma.
- If you are at risk from a blocked intestine (paralytic ileus).
- If you are suffering from severe diarrhoea caused by food poisoning or an infection.

- If you are unconscious (coma).
- If you are taking medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs) (e.g. phenelzine, tranylcypromine, moclobemide or selegiline) or have taken them in the last 10 days

Warnings and precautions

Special care should be taken with Pharma-Q Morphine Injection:

Tell your doctor if you have any of the following medical conditions:

- Hypothyroidism – underactive thyroid gland.
- Adrenocortical insufficiency – undersupply of corticosteroid hormones by the body.
- Impaired kidney or liver function.
- Enlarged prostate.
- Convulsions (fits and seizures).
- Shock (the symptoms of which include sweating, a fast pulse and cold, clammy skin).
- Inflammatory or obstructive bowel disorders.
- Myasthenia gravis – weakness of selected muscles.
- Lung and/or breathing disorders.
- Hypotension – low blood pressure (the symptoms of which include dizziness or light-headedness).
- Biliary tract disease.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.

- Abstinence symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the interval between doses.

Children and adolescents

- 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.

Other medicines and Pharma-Q Morphine Injection

Always tell your health care provider if you are taking any other medicine. (This includes all 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 which are used in the treatment of depression.
- Mono-amine oxidase inhibitors such as moclobemide or phenelzine (medicines used for depression).
- Phenothiazines which are medicines used to treat mental illnesses, including schizophrenia (e.g. chlorpromazine, haloperidol).
- Tranquillising medicines or sleeping tablets such as diazepam, nitrazepam and temazepam.
- Cimetidine (an anti-ulcer treatment).
- Dysrhythmic medicines to control heart rhythm or rate (e.g. mexiletine).
- Medicines used for diarrhoea (e.g. loperamide, kaolin).

- Medicines which are used as premedication before operations and after heart attacks such as atropine.
- Medicines used to treat vomiting or indigestion (e.g., domperidone or metoclopramide).
- Certain antibiotics, used to treat infections (e.g. ciprofloxacin and linezolid).
- Rifampicin to treat e.g. tuberculosis.
- Ritonavir, used in the treatment of HIV.
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with Pharma-Q Morphine Injection.
- Concomitant use of Pharma-Q Morphine Injection and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Pharma-Q Morphine Injection with alcohol

You should not drink alcohol whilst being given Pharma-Q Morphine Injection, as it will increase its effect.

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 Morphine Injection.

You will not be given Pharma-Q Morphine Injection during pregnancy and lactation since the safety and efficacy of Pharma-Q Morphine Injection has not been established.

Driving and using machines

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 provider not drive or operate machinery.

Pharma-Q Morphine Injection contains sodium

Pharma-Q Morphine Injection contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially sodium free.

3. How to receive Pharma-Q Morphine Injection

You will not be expected to give yourself Pharma-Q Morphine Injection. It will be given to you by a person who is qualified to do so.

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 and for how long you will receive Pharma-Q Morphine Injection.

For most conditions, Pharma-Q Morphine Injection is usually given as a continuous intravenous infusion or in divided doses throughout the day. However, in certain cases a single dose is required for the control of pain.

Pharma-Q Morphine Injection is administered either:

- directly into the muscle (intramuscular), beneath the skin (subcutaneous) or into sheath/membrane surrounding the spinal cord (intrathecal)
- as a slow injection directly into the vein (intravenous)
- as a slow intravenous infusion directly into the vein on a continuous basis.

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.

If you receive more Pharma-Q Morphine Injection than you should

Since a health care provider will administer Pharma-Q Morphine Injection, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

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

- Cold, clammy skin
- Confusion
- Convulsion
- Dizziness
- Drowsiness
- Low blood pressure
- Nervousness or restlessness
- Pinpoint pupils of eyes
- Slow heartbeat
- Slow or troubled breathing
- Weakness

If you missed a dose of Pharma-Q Morphine Injection

Since a health care provider will administer Pharma-Q Morphine Injection, it is unlikely that the dose will be missed.

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

4. Possible side effects

Pharma-Q Morphine Injection can have side effects. 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 health care provider for advice.

If any of the following happens, stop receiving Pharma-Q Morphine 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,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Pharma-Q Morphine Injection. You may need urgent medical attention or hospitalisation.

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

- Changes in heart rate and/or an awareness of your heart beating;
- Convulsions (fits or seizures);
- Low blood pressure (hypotension) which may make you feel faint;
- Your heart finding it difficult to pump blood around your body (circulatory failure) causing faintness, breathing difficulties, wheezing, difficulty in speaking, coughing up blood, excessive sweating and/or pale skin;
- Stomach pains, bloating, vomiting and constipation (obstructive bowel disorder);

- Withdrawal symptoms or dependence (symptoms may include body aches, shaking, flu-like symptoms, large pupils, an intense feeling of dissatisfaction, anxiety and irritability).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Physical and psychological dependence
- Drowsiness and confusion
- Feeling (nausea) or being sick (vomiting)
- Constipation
- Increased sweating
- Low body temperature (hypothermia)
- Raised pressure in the skull (increased intracranial pressure)
- Itching
- A feeling of dizziness or “spinning” (vertigo)
- Difficulty passing urine
- Inability to get an erection
- Facial flushing (warmth and redness of the skin)
- Tiredness (fatigue) and weakness
- Abstinence symptoms or dependence (see section 2 for symptoms)

Less frequent

- Loss of appetite
- Decreased libido (interest in sex)
- Changes of mood and mental depression
- Restlessness or nervousness

- Unusual excitement, especially in children
- False sense of wellbeing
- General feeling of discomfort or illness
- Seeing or hearing things that are not there (hallucinations)
- Difficulty to sleep (insomnia)
- Confusion
- Headaches
- Dizziness/light headedness on standing (orthostatic hypotension)
- Difficulty breathing
- Cramps or abdominal pain (urethral and biliary spasms or pancreatitis)
- Dry mouth
- An increase in liver enzymes may be noted during blood tests.
- Skin rash, itching, hives
- Constriction of the pupil (miosis)
- Involuntary eye movements (nystagmus)
- Very slow (bradycardia) or very fast (tachycardia) heartbeat
- Muscle stiffness
- Trembling or uncontrolled muscle movements
- Painful urination or frequent urge to urinate
- Redness, swelling, pain and irritation may occur at the site of the injection
- Stopping the medicine can lead to withdrawal symptoms such as agitation, anxiety, shaking or sweating. This can also happen to babies born to mothers addicted to morphine.

Frequency unknown

- Blurred vision
- Ringing or buzzing in the ears

- Being aware that your heart is beating, or the rate has changed (palpitations)
- Nightmares or unusual dreams
- Fits (convulsions)
- Increased blood pressure
- Respiratory failure
- Anorexia
- Muscle injury where your muscles break down (Rhabdomyolysis)
- Coma
- Kidney failure

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 Morphine Injection.

5. How to store Pharma-Q Morphine Injection

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light.
- Do not use after the expiry date stated on the ampoule or carton.

- Pharma-Q Morphine Injection will be stored in the pharmacy or in the hospital wards.

6. Contents of the pack and other information

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.

What Pharma-Q Morphine Injection looks like and contents of the pack

A clear colourless to slightly yellow solution.

1 ml amber ampoules in containers of 10 or 100.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (PTY) LTD

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Johannesburg

South Africa

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

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

Access to the corresponding Professional Information

Can be obtained on SAHPRA's website