

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S6****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****Pethidine hydrochloride****Sugar free****Read all of this leaflet carefully before you are given Pharma-Q Pethidine 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.

What is in this leaflet

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

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

Pharma-Q Pethidine Injection contains the active ingredient, pethidine hydrochloride which belongs to a group of medicines called opioid (narcotic) analgesics. It works by blocking the pain signals from reaching your brain is used for the relief of pain.

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.

2. What you need to know before you receive Pharma-Q Pethidine Injection

Pharma-Q Pethidine Injection should not be administered to you:

- If you are hypersensitive (allergic) to pethidine hydrochloride or any of the other ingredients of Pharma-Q Pethidine Injection (listed in section 6).
- 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 heart failure (when your muscles do not pump blood as well as it should) that resulted from lung disease.
- If you suffer from alcoholism.
- If you are suffering severe headaches or have suffered a head injury.
- If you suffer from a convulsive disorder (fits) such as epilepsy.
- If you suffer from a tumour of the adrenal gland known as phaeochromocytoma.
- If you are taking medicines known as Monoamine Oxidase Inhibitors (MAOI's) (medicines used to treat depression), or within 2 weeks of the discontinuation of such treatment (see Taking other medicines).
- If you are suffering from an attack of bronchial asthma or you are in heart failure secondary to chronic lung disease.
- If you are using antidepressants such as Selective Serotonin Reuptake Inhibitors (SSRIs) and St. John's wort or pain medication such as tramadol or triptans (used to

treat severe headaches/migraines).

- If you are taking a medicine called ritonavir (used to treat HIV infections).
- If you are in a coma.
- If you suffer from obstruction of the intestine due to paralysis of the intestinal muscles (paralytic ileus)
- If you suffer from an irregularly fast or erratic heartbeat (dysrhythmia) that affects the heart's upper chambers (supraventricular tachycardia).
- If you are pregnant or breastfeeding as safety has not been established (see Pregnancy and Breastfeeding).

Warnings and precautions

Tell your doctor or health care provider before being given Pharma-Q Pethidine Injection:

- If you suffer from opioid addiction.
- If you are in shock (the symptoms of which include sweating, a fast pulse and cold, clammy skin).
- If you suffer from thyroid problems.
- If you suffer from problems related to your adrenal gland (the organ responsible for stress levels), including adrenocortical insufficiency (a lack of the hormones produced by the adrenal gland).
- If you suffer from low blood pressure.
- If you are a male and suffer from problems with your prostate.
- If you suffer from problems with your gallbladder.
- If you suffer from problems with your bowel.
- If you have weak muscular movement and rapid fatigue of muscles under voluntary control (myasthenia gravis).
- If you have lung problems.
- If you have problems with your kidneys or liver.

- If you are in labour.
- If you are elderly or very ill.
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more of Pharma-Q Pethidine Injection to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- If you or your family have a history of mental health disorders (difficulty in thinking, understanding and judging clearly which causes loss of touch with reality), if you have depression, anxiety and suffer from alcohol and drug abuse.

Taking opioids or receiving opioids (as contained in Pharma-Q Pethidine Injection) over a long period of time produces:

- Tolerance (where you develop a requirement for increased doses of Pharma-Q Pethidine Injection to achieve the same pain-relieving effects.
- Dependence, such that when people stop taking/receiving opioids, they have physical and psychological symptoms of withdrawal (such as muscle cramping, diarrhoea, and anxiety).

Opioid addiction can cause life-threatening health problems, including the risk of overdose. Speak to your doctor if you experience any of these effects or if you are concerned.

Rarely, increasing the dose of Pharma-Q Pethidine Injection can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop using Pharma-Q Pethidine Injection. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability,

agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Children and adolescents

Great care should be taken if Pharma-Q Pethidine Injection is given to newborns or babies, as they may be more sensitive to breathing difficulties associated with Pharma-Q Pethidine Injection use.

Other medicines and Pharma-Q Pethidine Injection

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- **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, such as rasagiline or moclobemide) 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.

Tell your doctor if you are taking or have been given the following medicines as Pharma-Q Pethidine Injection can affect how they work:

- Selegiline or rasagiline (medicine used to treat Parkinson's disease);
- Ritonavir (medicine used to treat HIV);
- Cimetidine (medicine used to treat stomach ulcers) and cyclizine (medicine used to treat

nausea);

- Anxiolytics (medicine used to reduce anxiety) e.g. benzodiazepines such as diazepam;
- Hypnotics (medicine used to help you to sleep);
- CNS depressants (medicine that act on the brain and make you feel drowsy or faint).
These include sleeping pills, anti-histamines (medicines used to treat allergies) that make you drowsy, medicines used to treat certain mental disorders; alcohol;
- Phenytoin (medicine used to treat fits);
- Phenothiazines (medicines used to treat serious mental disorders);
- Medicine for depression (e.g. tricyclic antidepressants such as amitriptyline);
- Phenobarbitone (medicines used to treat epilepsy sedatives, sleeping tablets or barbiturates);
- Domperidone (medicines used to treat disorders of the gastrointestinal tract);
- Pain relievers used to treat moderate to severe pain (such as tramadol) and other opioid medicines;
- Ciprofloxacin (for antibiotic used to treat a number of bacterial infections);
- Mexiletine (medicine used to treat seriously irregular heartbeats);
- Citalopram (SSRIS) and St John's Wort used for the treatment of depression;
- Triptans (medicines used for the treatment of migraines).

Concomitant use of Pharma-Q Pethidine 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. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe Pharma-Q Pethidine Injection together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Pharma-Q Pethidine Injection with alcohol

You are advised not to drink alcohol during your treatment with Pharma-Q Pethidine Injection.

Pregnancy, breastfeeding and fertility

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 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 Pharma-Q Pethidine Injection should not be administered to you).

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.

Driving and using machines

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.

It is not always possible to predict to what extent Pharma-Q Pethidine Injection may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Pharma-Q Pethidine Injection affects them.

3. How to receive Pharma-Q Pethidine Injection

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

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

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.

Your doctor will give Pharma-Q Pethidine Injection to you as an injection into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly).

Your doctor will tell you how long your treatment with Pharma-Q Pethidine Injection will last. If you have the impression that the effect of Pharma-Q Pethidine Injection is too strong or too weak, tell your doctor or pharmacist.

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

Since a healthcare provider will administer Pharma-Q Pethidine Injection, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose. In the unlikely event of an overdose, you may experience any or the following symptoms:

- Muscular twitching
- Tremors
- Dilated pupils
- Convulsions

If you missed a dose Pharma-Q Pethidine Injection

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

If you stop using Pharma-Q Pethidine Injection

Do not suddenly stop using Pharma-Q Pethidine Injection. If you want to stop using Pharma-Q Pethidine Injection, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop using Pharma-Q Pethidine Injection.

4. Possible side effects

Pharma-Q Pethidine Injection can have side effects.

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 using Pharma-Q Pethidine Injection, please consult your health care provider for advice.

If any of the following happens, stop receiving Pharma-Q Pethidine Injection and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and 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 Pethidine 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:

- chest pain, angina, changes in the way your heart beats, for example, if you notice it beating faster, difficulty breathing;
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you;
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- drug withdrawal syndrome

Side effects with frequency unknown:

- addiction
- confusion
- mood changes (symptoms include feeling tense and restless)
- feeling of intense happiness (euphoria)
- hallucinations (seeing or hearing things that aren't real)
- dizziness
- drowsiness
- restlessness
- tremor or involuntary shaking
- convulsions
- feeling faint on standing up from a seated position

- headache
- fainting
- feeling weak
- a fast or slow heartbeat
- dry eye
- pin-point pupils, corneal reflex decreased
- a feeling of dizziness or spinning
- increased sensitivity to pain
- palpitations (an irregular heart rhythm or missed beats)
- low blood pressure, the symptoms of which include feeling dizzy or light-headed, feeling weak and fainting
- high blood pressure
- feeling sick (nausea)
- being sick (vomiting)
- constipation
- dry mouth
- facial flushing
- sweating
- slowed breathing
- spasms in the lower abdomen
- a red, itchy rash
- muscle twitching
- difficulty in passing urine
- reduced sex drive
- difficulty achieving or maintaining an erection
- hypothermia, the symptoms of which include shivering, drowsiness and feeling weak
- pain, redness or itching at the injection site

- abdominal pain, pancreatitis (inflammation of the pancreas).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Pharma-Q Pethidine Injection.

5. How to store Pharma-Q Pethidine Injection

Store all medicines out of reach of children.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

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.

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

Pharma-Q Pethidine Injection is a clear, colourless solution in clear, colourless glass ampoules.

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.

Not all packs and pack sizes may be marketed.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa

info@pharmaq.co.za

Tel: 011 247 1600

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Access to the corresponding Professional Information

<https://www.pharmaq.co.za>