PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S6

Pharma-Q Fentanyl 500 µg/10 ml Injection solution for injection

Pharma-Q Fentanyl 100 µg/2 ml Injection solution for injection

Fentanyl citrate

Sugar free

Pharma-Q Fentanyl Injection should only be used in facilities where immediate access to life support is available.

Read all of this leaflet carefully before you are administered Pharma-Q Fentanyl 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 Fentanyl Injection is and what it is used for
2. What you need to know before you are administered Pharma-Q Fentanyl Injection
3. How to receive Pharma-Q Fentanyl Injection
4. Possible side effects
5. How to store Pharma-Q Fentanyl Injection
6. Contents of the pack and other information

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

The active ingredient in Pharma-Q Fentanyl Injection is fentanyl. It belongs to a group of strong painkillers, which are also called opioids.

Pharma-Q Fentanyl Injection has been provided to you for pain relief during short surgical procedures and as a medicine given before administration of an anaesthetic.

2. What you need to know before you are administered Pharma-Q Fentanyl Injection

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

- if you are hypersensitive (allergic) to fentanyl, or any of the other ingredients of Pharma-Q Fentanyl Injection (listed in section 6).
- if you have previously had an allergic reaction to Pharma-Q Fentanyl Injection or a similar painkiller.
- If you suffer from abnormally slow or shallow breathing, especially in the presence of cyanosis (blue colour of the tissues, skin or gums caused by too little oxygen) and excessive mucous in the chest.
- If you have suffered any head injuries and conditions in which pressure inside the skull is raised.
- If you are having an acute attack of bronchial asthma (wheezing and difficulty in breathing).
- If you have suffered heart failure secondary to chronic lung disease.
- If you are taking mono-amine oxidase inhibitors (medicines used to treat depression) or within 14 days of stopping such treatment.

Warnings and precautions

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

- Pharma-Q Fentanyl Injection will be administered only by healthcare providers specifically trained to administer anaesthetics and also trained to manage the resultant breathing problems.
- Pharma-Q Fentanyl Injection may weaken breathing. This may also occur sometime after the operation. Therefore, you will remain under supervision for a while after the operation. If you experience severe drowsiness or breathing problems, tell a doctor or nurse immediately.
- If you have a lung disease or breathing problems, a brain disorder, impaired thyroid, liver or kidney function: always inform your doctor of this to ensure optimal care.
- If you use this medicine for a prolonged period, dependence can occur.
- If you are on long term opioid therapy (medicines used for pain) or have a history of opioid abuse, you may require higher doses.
- Pharma-Q Fentanyl Injection will be used with caution in patients with abnormal heart rhythms and abnormally slow pulse rate.
- If you suffer from muscle rigidity associated with reduced functioning of the lungs and/or your breathing stops, sudden, uncontrolled cramps in the voice box and sudden, uncontrolled narrowing of the airways, you will be given muscle relaxants.
- Pharma-Q Fentanyl Injection will be used with caution if you suffer from obstructive bowel disease and myasthenia gravis (muscle disorder causing weakness).
- The depressant effects are enhanced by central nervous system depressants such as alcohol, anaesthetics, hypnotics (medicines used for sleep disorders), sedatives (medicines used to induce sleep), phenothiazines (medicines used to treat depression) and meprobamate (medicine used to treat pain).

- Pharma-Q Fentanyl Injection will be given with caution or in reduced doses if you suffer from under active thyroid, decreased functioning of the adrenal gland, impaired kidney or liver function, enlarged prostrate or shock, elderly or debilitated patients.
- Repeated use of opioid painkillers may result in the medicine being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Pharma-Q Fentanyl Injection, it is important that you consult your healthcare provider.
- Being given Pharma-Q Fentanyl Injection regularly, particularly for a long time, can lead to addiction. Your healthcare provider should have explained how long you will be given Pharma-Q Fentanyl Injection for and when it is appropriate to stop, how it is done safely.
- Addiction can cause withdrawal symptoms when you are stopped being given this medicine. 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 healthcare provider will discuss with you how your dose will be gradually reduced before stopping Pharma-Q Fentanyl Injection. It is important that you should not stop being given Pharma-Q Fentanyl Injection suddenly as you will be more likely to experience withdrawal symptoms.
- Sometimes, increasing the dose of Pharma-Q Fentanyl Injection can make you more sensitive to pain. If this happens, you need to speak to your healthcare provider about your treatment.

Children and adolescents

Pharma-Q Fentanyl Injection should not be given to children younger than 2 years of age.

Other medicines and Pharma-Q Fentanyl Injection

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

Effect of other medicines on Pharma-Q Fentanyl Injection:

- ***Central nervous system depressant medicines such as:***
    - Certain medicines for depression called MAO inhibitors that should not be combined with Pharma-Q Fentanyl Injection. These medicines should not be taken in the 2 weeks before Pharma-Q Fentanyl Injection is given.
    - Certain other medicines for depression, called SSRIs or SNRIs.
    - Barbiturates (group of medicines used for anaesthesia, sedation, seizures etc.).
    - Benzodiazepines (medicines used for anxiety, insomnia etc.).
    - Tricyclic antidepressants (medicines used to treat depression).
    - Phenothiazines (medicines used to treat mental disorders).
    - Hypnotics (medicines used for sleep disorders).
    - Opioid premedication (medicines used for pain before anaesthetic is given).
    - Neuroleptics (medicines used to treat confusion, hallucinations etc).
    - Halogenic gases (Fluorine, Chlorine, Bromine, Iodine and Astatine).
    - Other non-selective central nervous system depressants (e.g. alcohol).

May increase the breathing problems caused by this medicine. If you have received such medicines, the dose of Pharma-Q Fentanyl Injection required will be less than usual.

- ***Other medicines such as:***
    - Itraconazole, fluconazole, voriconazole or ketoconazole (medicines used to treat fungal infections).
    - Oral ritonavir (medicine used for HIV infections and AIDS).
    - Erythromycin (antibiotic).
    - Diltiazem (medicine used for the heart).
    - Cimetidine (anti-ulcer medicine).

May also affect the way this injection works and dose reductions or adjustments may be required.

Effects of Pharma-Q Fentanyl Injection on other medicines:

Following concomitant administration:

- The dose of other CNS-depressant medicines may need to be reduced.
- It may interact with etomidate and intravenous midazolam and dosages may need reduction or adjustment.

Pharma-Q Fentanyl Injection with food, drink and alcohol

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

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 Fentanyl Injection.

- You will not be given Pharma-Q Fentanyl Injection if you are pregnant or breastfeeding since the safety and efficacy has not been established.
- The potential risk to humans is unknown but it may cross the placenta in early pregnancy and affect your baby.
- This medicine may pass into your breast-milk. Therefore, nursing is not recommended for 24 hours after you have been given this medicine.
- Administration during childbirth (including caesarean section) is not recommended because it may cross the placenta and cause breathing problems to the foetus.
- If it is nevertheless administered, an antidote for the child will always be at hand.

Driving and using machines

You should only drive or operate machinery if 24 hours has elapsed after you have been given Pharma-Q Fentanyl Injection.

3. How to receive Pharma-Q Fentanyl Injection

You will not be expected to give yourself Pharma-Q Fentanyl Injection. Pharma-Q Fentanyl 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 Fentanyl Injection:

- Your dose will be individualized according to your age, body weight, physical status, underlying medical conditions, use of other medicines and on the kind of anaesthesia you require.
- Your initial dose will be reduced if you are old or debilitated.
- The effects of your initial dose will be taken into account when determining your next dose.
- To avoid an abnormally slow pulse rate, a small dose of an anti-cholinergic (a substance which stops the passage of certain nerve impulses) will be given into the vein just before the start of anaesthesia.
- A medicine called droperidol may be given to you to prevent nausea and vomiting.
- Concomitant use with droperidol may also cause a state of neurolept-analgesia and/or neurolept-anaesthesia (no pain, altered awareness and memory) so that various diagnostic or minor surgical procedures can be carried out.

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

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

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

If you missed a dose of Pharma-Q Fentanyl Injection

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

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

4. Possible side effects

Pharma-Q Fentanyl Injection can have side effects.

Not all side effects reported for Pharma-Q Fentanyl Injection are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Pharma-Q Fentanyl Injection, please consult your health care provider for advice.

If any of the following happens, stop receiving Pharma-Q Fentanyl 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 are all very serious side effects. If you have them, you may have had a serious reaction to Pharma-Q Fentanyl 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:

- abnormally slow pulse rate, increased heart rate and abnormal heart rhythms.
- difficulty breathing; too fast or too slow breathing.

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

Tell your doctor if you notice any of the following:

Frequent

- feeling sick (nausea), being sick (vomiting)
- muscle stiffness (which may involve your chest muscles)
- involuntary, repetitive body movements
- drowsiness
- dizziness
- problems with vision
- rapid or slow heartbeats
- irregular heartbeats
- low or high blood pressure
- pain in your veins
- choking caused by cramping (spasm) of the muscles in your throat
- difficulty in breathing or wheezing
- stop breathing for a short period of time (apnoea)
- skin rash
- confusion after the operation.

Less frequent

- changes in blood pressure
- breathing complications
- breathing faster than normal
- fall in body temperature below normal or chills

- headache
- swelling and clotting in a vein
- hiccups
- mood elevation
- agitation after operation.

Frequency unknown

- convulsions (fits or seizures)
- loss of consciousness
- muscle twitching
- stopping of the heart (cardiac arrest)
- slow or shallow breathing
- itching of the skin
- unusual increase in sense of smell, taste, touch, feel (e.g. feel of pain) or hearing
- cough
- constipation
- delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- dependence and addiction
- increased risk of abdominal pain, including pancreatitis.

If you received Pharma-Q Fentanyl Injection with a tranquiliser (such as droperidol) and you notice any of the following effects, tell your doctor:

- shivering and restlessness
- seeing or hearing things that aren’t there (hallucinations)
- unusual movements, including trembling and shaking of the hands and fingers, twisting

movements of the body, shuffling walk and stiffness of the arms and legs.

Drug withdrawal: When you are stopped being given Pharma-Q Fentanyl Injection, you may experience drug withdrawal symptoms, which include nausea, vomiting, chills, restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

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 Fentanyl Injection.

5. How to store Pharma-Q Fentanyl 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.

6. Contents of the pack and other information

What Pharma-Q Fentanyl Injection contains

- The active ingredient is fentanyl citrate.

  Pharma-Q Fentanyl 500 µg/10 ml Injection: Each 10 ml contains the equivalent of 500 µg fentanyl base as fentanyl citrate.

Pharma-Q Fentanyl 100 µg/2 ml Injection: Each 2 ml contains the equivalent of 100 µg fentanyl base as fentanyl citrate.

- The other ingredient is: Water for injections.

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

A clear, colourless solution in amber glass ampoules.

Pharma-Q Fentanyl 500 µg/10 ml Injection: Amber 10 ml ampoules in boxes of 10.

Pharma-Q Fentanyl 100 µg/2 ml Injection: Amber 2 ml ampoules in boxes of 10.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (PTY) LTD

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Johannesburg

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Registration numbers

Pharma-Q Fentanyl 500 µg/10 ml Injection: 29/2.7/0604.

Pharma-Q Fentanyl 100 µg/2 ml Injection: 29/2.7/0605.

Access to the corresponding Professional Information

To be confirmed.