Proprietary name:	**Pharma-Q Hydroxyzine Injection 100 mg/2 ml**
Dosage form:	Injection
Active ingredient:	Hydroxyzine hydrochloride
Strength per dosage unit:	Each 2 ml contains hydroxyzine hydrochloride 100 mg/2ml

1.3 South African labelling and packaging

1.3.2 Patient Information Leaflet

PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

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

Read all of this leaflet carefully before you are given Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

- Keep this leaflet. You may need to read it again.
- [~~It contains information on **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** which is part of your hospital treatment.~~]
- If you have further questions, please ask your doctor or your pharmacist.
- **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** 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 HYDROXYZINE INJECTION 100 mg/2 ml CONTAINS:

Each ampoule contains hydroxyzine hydrochloride 100 mg/2 ml with benzyl alcohol 0,9 % v/v

The other ingredients are:

- Benzyl alcohol.
- Nitrogen.
- Sodium hydroxide.
- Water for injection.

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4. WHAT PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml IS USED FOR:

Hydroxyzine hydrochloride is known as a piperazine derivative. It can be used as an antihistamine (medicine used to treat allergy) as well as an anxiolytic (medicine used to treat anxiety and tension).

Your doctor may therefore prescribe **Pharma-Q Hydroxyzine Injection 100 mg/2 ml:**

- to control your symptoms of nausea, vomiting or anxiety before and after an operation.
- to control your symptoms of Meniere's disease and related disorders (disorder of the inner ear in which there is dizziness, ringing in the ears and loss of hearing).
- in combination with other medicines; to treat allergic conditions, like rash or itching.

5. BEFORE YOU RECEIVE PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml:

You [~~will~~] should not be given **Pharma-Q Hydroxyzine Injection 100 mg/2 ml:**

- if you are allergic to hydroxyzine hydrochloride, cetirizine, any other piperazine derivatives or any other ingredients in this medicine (see **WHAT PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml CONTAINS**)
- if you have porphyria (a disease which causes stomach pain, constipation, changes in the colour of urine, skin rashes and disturbed behaviour).
- if you cannot breathe properly or have conditions like asthma etc.
- if you have had any bad reaction to a blood transfusion, caused by a blood type disorder (blood types mixed but not compatible).
- if the patient is a premature infant or neonate/(newborn) as this group of patients may be more prone to adverse effects.
- if you are pregnant or breastfeeding since the safety in pregnancy and breastfeeding has not been established (see **Pregnancy and Breastfeeding**).

Pharma-Q Hydroxyzine Injection 100 mg/2 ml will be injected directly into a muscle.

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Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

- may depress (slow down) your central nervous system which may lead to drowsiness and poor concentration.
- may become worse if you are also taking alcohol, other sleep inducing medicines, other pain relieving medicines, other anti-anxiety medicines or medicines used to treat mental disorders (see **Taking other medicines with Pharma-Q Hydroxyzine Injection 100 mg/2 ml**).
- if you are affected you should not drive or operate hazardous machinery (see **Driving and using machinery**).
- may affect you if you are elderly, as you may be more prone to adverse effects (e.g. a drop in your blood pressure).
- may affect you if you have increased pressure inside the eye/glaucoma, problems with passing urine, an enlarged prostate gland (in males), or if you have digestive problems of the stomach and intestines.
- may affect you if you have fits/epilepsy and severe heart disorders.
- your dosage will therefore be decreased if you are elderly (see **HOW TO RECEIVE PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml**).
- your dosage frequency will be decreased if you have problems of the liver (e.g. destruction of bile ducts in the liver causing a build up of bile).

Pregnancy and Breastfeeding:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

- You will not be given this medicine if you are pregnant or breastfeeding since the safety in pregnancy and breast-feeding has not been established (see **You should not be given Pharma-Q Hydroxyzine Injection 100 mg/2 ml**).
- It may affect your unborn baby if it used during late pregnancy.

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 Hydroxyzine Injection 200 mg/2 ml**.

Driving and using machinery:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml may cause drowsiness and poor concentration, which may become worse if you are taking alcohol or other medicines which slow down your responses. You will be advised not to drive or operate hazardous machinery because loss of concentration could lead to serious accidents (see **Special care should be taken with Pharma-Q Hydroxyzine Injection 200 mg/2 ml**).

Taking other medicines with Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

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

(This includes complementary or traditional medicines.)

Always tell your doctor or pharmacist about any other medication or herbal preparations that you are taking. These medicines may interact with **Pharma-Q Hydroxyzine Injection 100 mg/2 ml**, or **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** may interact with these medicines.

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

Interaction with different medicines:

Central nervous system depressant agents (slow down your responses):

Pharma-Q Hydroxyzine Injection 100 mg/2 ml may increase the calming or sleeping effects of medicines which slow down your responses such as;

- Alcohol,
- Other sleep inducing medicines,
- Other pain relieving medicines,
- Other anti-anxiety medicines,
- Medicines used to treat mental disorders, (see **Special care should be taken with Pharma-Q Hydroxyzine Injection 200 mg/2 ml**).

  Your dosages will be adjusted if you are concurrently taking these medicines.

Mono-amine oxidase inhibitors (medicines used to treat mental depression):

- You may experience more side effects such as dry mouth, increased heart rate, urinary retention, decreased bowel movements etc. if you use these medicines together

Anticonvulsants and antibiotics:

- If you are using phenytoin to control your fits or convulsions, this medicine may counteract the effects of phenytoin If you are using certain antibiotics (e.g. aminoglycoside antibiotics), this medicine may mask the warning signs of damage to the ear caused by these antibiotics.

General interactions:

- If your doctor sends you for a skin test for allergies, **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** should be stopped a few days before the test as it may interfere with the results.

4. HOW TO RECEIVE PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml:

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

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Always receive **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Hydroxyzine Injection 100 mg/2 ml will be given to you by a doctor or nurse in a hospital setting. Your doctor will choose the dose that is right for you.

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

- will only be injected into a muscle.

If you have the impression that the effect of Pharma-Q Hydroxyzine Injection 100 mg/2 ml is too strong or too weak, talk to your doctor or pharmacist.

If you are given more Pharma-Q Hydroxyzine Injection 100 mg/2 ml 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.

Pharma-Q Hydroxyzine Injection 100 mg/2 ml overdose:

- you may have increased slowing down of your responses and other adverse effects such as dry mouth, stomach and bladder problems etc.
- overdose may be fatal in infants and children, as the responses are more stimulated, causing effects such as loss of control over body movements, excitement, false perceptions, tremors, mental disorders, fits and very high fever. Children may go into a deep coma or may get heart arrest.
- in adults, slowing down of your responses is more common with drowsiness, coma, fits, failure to breathe or possible heart arrest.
- if you have fits, you will be given diazepam.

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- your other treatment will be aimed at treating your symptoms and giving you supportive medical therapy (e.g. oxygen, fluids and controlling your fever)

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

If you missed a dose of Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

If you think that you did not receive a dose of **Pharma-Q Hydroxyzine Injection 100 mg/2 ml**, contact your doctor.

If you have any further questions on the use of **Pharma-Q Hydroxyzine Injection 100 mg/2 ml**, ask your doctor, nurse, or pharmacist.

5. POSSIBLE SIDE EFFECTS:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml can have side effects.

Not all side effects reported for **Pharma-Q Hydroxyzine Injection 100 mg/2 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Hydroxyzine Injection 100 mg/2 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following serious side effects occur, stop receiving Pharma-Q Hydroxyzine Injection 100 mg/2 ml 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.

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These serious side effects and you may have had an allergic reaction to **Pharma-Q Hydroxyzine Injection 100 mg/2 ml.** You may need urgent medical care or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- decreased heart rate followed by increased heart rate with palpitations and abnormal heart rhythms and a drop in blood pressure
- yellowing of the skin and eyes, also called jaundice.

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

Tell your doctor as soon as possible if you notice any of the following:

The following side effects may occur, but the frequencies are unknown:

Cardio-vascular disorders:

Frequency unknown:

In high doses, decreased heart rate followed by increased heart rate with palpitations and abnormal heart rhythms and a drop in blood pressure.

Blood and the lymphatic system disorders:

Frequency unknown:

Decreased white blood cells called neutrophils, decreased white blood cells called leukocytes, lack of red blood cells due to destruction of circulating cells and too few blood platelets (these may have an immune basis).

Nervous system disorders:

Frequency unknown:

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State of calmness, varying from slight drowsiness to deep sleep, lack of energy, dizziness, inco-ordination, fatigue, shakes and fits. Calming effect may diminish after a few days of treatment. Increased stimulation of the central nervous system, especially with high doses and in children; giving rise to sleep disorders, nervousness, irritability, shakes, nightmares, false perceptions and fits. Movement disorders may occur, as well as headache and tingling, numbness, pins and needles.

Gastro-intestinal disorders:

Frequency unknown:

Dry mouth, sluggish digestive tract resulting in constipation and increased reflux of stomach acid, nausea, vomiting, diarrhoea and stomach pain.

Skin and subcutaneous tissue disorders:

Frequency unknown:

Allergic reactions.

Respiratory disorders:

Frequency unknown:

Thickened secretions of mucous and tightness of the chest.

Renal and urinary disorders:

Frequency unknown:

Difficulty in passing urine or abnormal holding of urine.

Hepato-biliary disorders:

Frequency unknown:

Yellow pigmentation of skin and eyes /(jaundice) which may be an allergic reaction.

Eye disorders:

Frequency unknown:

Blurred vision and increased sensitivity of the eyes to light.

Ear and labyrinth disorders:

Frequency unknown:

Ringing in the ears.

General disorders and administrative site conditions:

Frequency unknown:

Local discomfort at the site of injection.

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

6. STORING AND DISPOSING OF PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml:

Store at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

7. PRESENTATION OF PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

2 ml clear, colourless glass ampoules in containers of 10 or 100.

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8. IDENTIFICATION OF PHARMA-Q HYDROXYZINE INJECTION 100 mg/2 ml:

Pharma-Q Hydroxyzine Injection 100 mg/2 ml:

Clear, colourless solution, in clear colourless glass ampoules.

9. REGISTRATION NUMBER:

31/2.6.3/0070.

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa.

11. DATE OF PUBLICATION:

Original date of registration: 07 November 1996.

Revised package insert approval: 03 October 2014.

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