CLEAN COPY OF THE PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Atropine Injection 0,5 mg/1 ml solution for injection

Pharma-Q Atropine Injection 1,0 mg/1 ml solution for injection

Read all of this leaflet carefully before you are given Pharma-Q Atropine Injection

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Pharma-Q Atropine 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.

1. WHAT PHARMA-Q ATROPINE INJECTION CONTAINS:

The active substance is atropine sulphate.

Pharma-Q Atropine Injection 0,5 mg/1 ml:

Each 1 ml ampoule contains 0,5 mg of atropine sulphate.

Pharma-Q Atropine Injection 1,0 mg/1 ml:

Each 1 ml ampoule contains 1,0 mg of atropine sulphate.

The other ingredients are acid sulphate, sodium chloride, water for injection.

2. WHAT PHARMA-Q ATROPINE INJECTION IS USED FOR:

Atropine sulphate belongs to a class of medicines called Belladonna alkaloids. It is called an antimuscarinic agent. It works by stopping some of the actions of a naturally occurring substance in our body called acetylcholine. By blocking this substance, it temporarily blocks some nerve endings. This in turn makes:

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- some muscles (such as the stomach and intestine) relax
- stops or reduce glands from secreting certain substances (saliva, mucous, stomach acid etc.)
- speeds up the heart (used during surgery to maintain proper heart function or used during emergencies involving the heart).

Atropine sulphate is a useful antidote against certain types of poisons and can also be used to treat stiffness and tremors in people who have Parkinson's disease.

Atropine sulphate has many uses in the human body and this allows it to be useful during surgery.

Therefore, your doctor may prescribe **Pharma-Q Atropine Injection** for you as:

- pre-medication before anaesthesia
- to treat a slow heart beat or a heart which has stopped pumping altogether
- to treat certain kinds of poisoning
- to control the side effects of neostigmine (a medicine which can increase nerve impulses to the muscles).

3. BEFORE YOU ARE GIVEN PHARMA-Q ATROPINE INJECTION:

You should not be given Pharma-Q Atropine Injection:

- if you are allergic to atropine sulphate or to any ingredients of this medicine (see **WHAT PHARMA-Q ATROPINE INJECTION CONTAINS**)
- if you have closed-angle glaucoma (an eye condition that causes sudden blurred vision with pain and redness)
- if you have increased pressure inside your eye
- if you have enlargement of the prostate gland (in males) as this may cause difficulty in passing urine
- if you have narrowing of the entrance between the stomach and intestine due to ulcers in the stomach or if you have severe constipation and bloating caused by inactivity of your

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intestines

- if you have a condition that causes extreme tiredness or severe muscle weakness
- if you have problems with the blood supply to your heart or heart failure
- if you are pregnant or breast-feeding since safety in pregnancy and breast-feeding has not been established (see **Pregnancy and Breastfeeding**).

Tell your doctor or healthcare professional before being given Pharma-Q Atropine Injection:

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

- if you are old or if it is given to your children since they are more susceptible to its adverse effects
- if you have inflammation of the bowel or any obstruction in the intestines
- if you have acid reflux or stomach ulcers
- if you have diarrhoea
- if you have a fever as it may increase your fever
- if you have an increased heart rate, insufficient blood going to the heart, heart failure or if you have an excess of thyroid hormone
- if you are undergoing surgery to the heart, as it may further increase your heart-rate
- if you are having a heart attack as it may aggravate the attack and reduce the blood supply to the heart
- if you have a high blood pressure.

Also take special care with Pharma-Q Atropine Injection:

- if you are given high doses, it may cause a drop in your blood pressure when you stand up
- if you have a fever or if your child has a fever, it will not be given, as it may further increase the fever
- if you are being treated for Parkinson’s disease, your dosages will be increased

gradually. If your treatment needs to be changed, it will also be done gradually.

Pharma-Q Atropine Injection will not be abruptly discontinued. If increased doses cause severe mental disturbances, the medicine will be discontinued, but minor reactions will be controlled by reducing your dose until tolerance has developed

- if the patient has Down's syndrome (genetic mental disability), they will be more prone to the adverse effects of this medicine, whereas patients with albinism (pigment disorder of the skin) may be more resistant.

Pregnancy and Breastfeeding

You will not be given this injection if you are pregnant or breastfeeding (see **You should not be given Pharma-Q Atropine Injection**) since safety in pregnancy and breastfeeding has not been established

It may cross the placenta and be excreted into your breast milk.

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 Atropine Injection.**(

Driving and using machinery:

Pharma-Q Atropine Injection may cause mental confusion, especially if you are old. You will be advised not to drive or operate hazardous machinery because loss of concentration could lead to serious accidents.

Taking other medicines with Pharma-Q Atropine Injection:

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

(This includes complementary or traditional medicines.)

The effects of **Pharma-Q Atropine Injection** may be increased by the concurrent administration of these medicines:

- amantadine (medicine used to treat Parkinson's disease)
- some antihistamines (medicines used to treat allergies)

- butyrophenones (medicines used to treat mental illness)
- phenothiazines (medicines used to treat mental illness)
- tricyclic antidepressants (medicines used to treat depression).

These medicines may also affect emptying of the stomach into the intestine and may therefore affect the absorption of other medicines.

4. HOW TO RECEIVE PHARMA-Q ATROPINE INJECTION:

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

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

Pharma-Q Atropine Injection 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 Atropine Injection:

- may be given as pre-medication before you are given an anaesthetic
- may be given into the muscle, into the vein or under the skin
- may also be given to increase the heart rate or stabilize abnormal rhythms of the heart
- may be given to reverse the effects of certain muscle relaxers used during surgery
- may be used as an antidote to treat poisoning
- prevents the heart from slowing down and reduces bodily secretions like saliva, or mucous to make surgery easier
- dosages will be calculated by your doctor
- dosages for adults and children will be different.

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

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If you are given more Pharma-Q Atropine 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.

Pharma-Q Atropine Injection overdose:

For symptoms see **POSSIBLE SIDE EFFECTS** and **Special care should be taken with Pharma-Q Betamethasone Injection 4 mg/ml**.

Toxic doses of **Pharma-Q Atropine Injection** may cause:

- increased heart rate and rapid breathing
- high fever
- stimulation of the central nervous system, causing restlessness, confusion, excitement, mental disorders, false perceptions and occasionally fits
- a rash may appear on the face or upper body.

In severe intoxication:

Stimulation of the nervous system may give way to central nervous system depression, resulting in coma, failure to breath, failure of the blood to circulate and death.

Treatment of **Pharma-Q Atropine Injection** overdose:

- your symptoms will be treated and you will be given medical support (e.g. oxygen and ventilation)
- you may be given diazepam (medicine used to treat anxiety) to control marked excitement and fits.

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

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

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

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

5. POSSIBLE SIDE EFFECTS:

Pharma-Q Atropine Injection can have side effects.

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

If any of the following serious side effects occur, stop receiving Pharma-Q Atropine 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 allergic reaction to **Pharma-Q Atropine Injection.** You may need urgent medical attention 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
- Dilatation of the pupils with loss of vision, increased pressure inside the eye and sensitivity to sunlight.

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:

- Confusion, giddiness and staggering
- Dryness of the mouth with difficulty in swallowing and talking, thirst, vomiting, as well as decreased movement of the stomach and intestines, leading to constipation. Increased chest pain due to increased gastric reflux.
- Reduced mucous secretions from the lungs.
- Redness and dryness of the skin.
- Difficulty in urinating.

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

6. STORING AND DISPOSING OF PHARMA-Q ATROPINE INJECTION:

Store at or below 25 °C.

Protect from light.

Keep out of reach of children.

7. PRESENTATION OF PHARMA-Q ATROPINE INJECTION:

10 x 1 ml clear colourless glass ampoules

8. IDENTIFICATION OF PHARMA-Q ATROPINE INJECTION:

Pharma-Q Atropine Injection is a clear colourless solution filled into clear colourless glass ampoules.

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9. REGISTRATION NUMBERS:

Pharma-Q Atropine Injection 0,5 mg/1 ml: 31/5.4/0206

Pharma-Q Atropine Injection 1,0 mg/1 ml: 31/5.4/0207

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:

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