MODULE 1.3.2 CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Pharma-Q Diazepam Injection 10 mg/2 ml (solution for injection)

Read all of this leaflet carefully before you are given Pharma-Q Diazepam Injection 10 mg/2 ml

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Pharma-Q Diazepam Injection 10 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 DIAZEPAM INJECTION 10 mg/2 ml CONTAINS:

The active substance is: Diazepam.

Each 2 ml of solution contains 10 mg of Diazepam.

The other ingredients are:

- Benzoic acid
- Benzyl alcohol
- Ethanol
- Hydrochloric acid
- Propylene glycol
- Sodium hydroxide

- Water for injection.

4. WHAT PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml IS USED FOR:

Pharma-Q Diazepam Injection 10 mg/2 ml belongs to a group of medicines called benzodiazepines. It can cause you to **fall asleep** and it can also have a **calming effect** on you.

Your doctor may prescribe **Pharma-Q Diazepam Injection 10 mg/2 ml** in the following circumstances:

- If you need a calming agent in anxiety and tension states
- If you need a sedative (sleeping tablet)
- If you need to be calmed before any surgical and other procedures or need to be sedated while you are in hospital
- If you have a severe muscle spasm as in tetanus
- If you are suffering alcohol withdrawal symptoms as this medicine is used to manage alcohol withdrawal syndrome
- If you suffer from status epilepticus (seizures) as this medicine is used for the control of status epilepticus.
- If you are in labour and need medicine to facilitate labour.

Pharma-Q Diazepam Injection 10 mg/2 ml will only be prescribed by your doctor when your disorder is severe, disabling or subjecting you to extreme stress.

5. BEFORE YOU RECEIVE PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml:

You should NOT be given Pharma-Q Diazepam Injection 10 mg/2 ml:

- If you are allergic to diazepam or benzodiazepines or to any ingredient used in this medicine (see **WHAT PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml CONTAINS**)
- If you are an infant. Your infant will not be put on therapy with this medicine as infants are unable to breakdown diazepam resulting in toxicity
- If you are pregnant as safety and efficacy has not been established (see **Pregnancy and Breastfeeding**)
- If you are breast-feeding (see **Pregnancy and Breastfeeding**).

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

Special care should be taken with Pharma-Q Diazepam Injection 10 mg/2 ml:

- If you suffer from impaired liver, kidney, respiratory function or closed-angle glaucoma (increased pressure in the eye), caution will be taken by your doctor when prescribing it to you
- If you are old or debilitated, you may be especially sensitive to its side-effects (over sedation, difficulty in breathing and loss of muscle co-ordination)
- If you are taking other depressants which slows down the central nervous system like alcohol, antidepressants, anti-histamines, general anaesthetics, other sedatives or pain killers, they will enhance the sedation or respiratory and cardio-vascular depressive action of this medicine
- If you are suffering from psychosis (severe mental disorders), this medicine will be avoided, unless there is a marked component of anxiety in your illness as this injection may precipitate suicidal or aggressive behaviour
- If you suffer from pre-existing central nervous system depression or coma, have difficulty in breathing, are short of breath or have weakness of your chest muscles that help you

breath or sleep apnoea (a condition where your breathing stops for short spells when you are asleep), its use will be avoided

- If you suffer from chronic pulmonary insufficiency (long term breathing disorders), it will be administered with great care
- If you have suffered from any changes in your brain, particularly arteriosclerosis (a narrowing of the blood vessels), this medicine will be used with caution
- If you are on prolonged and high doses, there exists a potential for abuse and dependence
- You may suffer from withdrawal symptoms after long periods of ordinary therapeutic doses
- If you suffer from or have a history of alcohol or drug abuse, this medicine will be used with extreme caution.

Dependence

- There exists a potential for abuse and dependence, especially with prolonged use and high doses
- The risk of dependence is greater if you have a history of alcohol or drug abuse
- Once dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms
- These may consist of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability
- In severe cases the following symptoms may occur: Derealisation (loss of sensation regarding your surroundings), depersonalisation (loss of contact with your own personal feelings), hyperacusis (abnormal awareness to hearing-intolerance to normal sounds), numbness and tingling of extremities, hypersensitivity to light, noise and physical contact and hallucinations (false perceptions) or epileptic seizures (fits).

Rebound effects

- Sometimes, the symptoms that led to your treatment with **Pharma-Q Diazepam Injection 10 mg/2 ml** may recur in an enhanced form upon withdrawal of treatment
- These symptoms may be accompanied by other reactions, including mood changes, anxiety and restlessness
- Due to this risk, your dosage will be decreased gradually (see **Duration of treatment**).

Pregnancy and Breastfeeding:

Pharma-Q Diazepam Injection 10 mg/2 ml:

Pregnancy:

- You will not be given this medicine if you are pregnant (see **You should NOT be given Pharma-Q Diazepam Injection 10 mg/2 ml**)
- If you use this medicine during the first trimester of your pregnancy, your infant may be at increased risk of developing deformities.

Breastfeeding:

- You will not be given this medicine while you are breast-feeding since diazepam and its metabolites crosses into breast-milk and may harm the baby (see **You should NOT be given Pharma-Q Diazepam Injection 10 mg/2 ml**) Infants may be unable to break down this medicine.

Pharma-Q Diazepam Injection 10 mg/2 ml:

Use during labour:

- If you are given this medicine in the third trimester of your pregnancy or during labour, it may be associated with neonatal withdrawal syndrome or the floppy infant syndrome (decreased muscle tone) in some infants

- Administration during labour may cause breathing and feeding difficulties in your infant, low body temperature, poor muscle tone and an increase in foetal heart rate
- Your infants may also be at risk of slow development in the initial years but that may be corrected by 4 years of age.

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 Diazepam Injection 10 mg/2 ml.**

Driving and using machinery:

Pharma-Q Diazepam Injection 10 mg/2 ml may make you sleepy, forgetful or affect your concentration and coordination. This may affect your performance at skilled tasks, e.g. driving or operating machinery. Your doctor should advise you when you can start these again. You should always be accompanied home by a responsible adult after your treatment.

Taking other medicines with Pharma-Q Diazepam Injection 10 mg/2 ml:

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

Pharma-Q Diazepam Injection 10 mg/2 ml:

May interact with other medicines. Enhanced sedation (sleep) or respiratory depression (breathing problems) may occur if given with medicines that cause central nervous system (CNS) depression or with medicines that interfere with its breakdown.

The following medicines may interact with **Pharma-Q Diazepam Injection 10 mg/2 ml**. Its effects may be enhanced or reduced by these medicines:

- **Narcotic analgesics and other sedatives and muscle relaxants:** Additive sedative effect (e.g. fentanyl)
- **Anti-biotics:** Enhanced effect (e.g. erythromycin, clarithromycin)
- **HIV medicines** Enhanced effect (e.g. ritonavir)
- **Anti-fungals**: Enhanced effect (e.g. itraconazole, ketoconazole)
- **Anti-epileptics:** Reduced effect (e.g. carbamazepine, phenobarbitone and phenytoin)
- **Anti-depressants:** Additive effects (e.g. Fluoxetine, fluvoxamine)
- **Anti-histamines and other cold and flu preparations:** Additive effects (e.g. diphenhydramine)
- **Antihypertensives and medicines used for the heart:** Increased effects (e.g. propranolol, diltiazem, verapamil)
- **Anti-Parkinson's medicine:** Reduces the effect of levodopa.
- **Gastro-intestinal agents**: Increased effects (e.g. cimetidine, omeprazole)
- **General anaesthetics**: Increased effects (e.g. halothane)
- **Alcohol**: Additive effects.

Alcohol may increase the sedative effects of **Pharma-Q Diazepam Injection 10 mg/2 ml** and should therefore be avoided. Do not drink alcohol until your doctor tells you it is all right to do so.

6. 4. HOW TO RECEIVE PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml:

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

Always receive **Pharma-Q Diazepam Injection 10 mg/2 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

Pharma-Q Diazepam Injection 10 mg/2 ml 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 Diazepam Injection 10 mg/2 ml:

- Treatment will be started with the lowest recommended dose
- Your doctor will calculate the correct dosage for you and also determine how it will be administered
- The maximum dose will not be exceeded
- Dosage reduction may be required if you suffer from liver or kidney dysfunction
- It will be given by deep intramuscular (intro the muscle) or slow intravenous (into the vein) injection
- Intravenous injection will be carried out slowly to reduce the risk of thrombophlebitis (inflammation of the vein or forming of a clot) or breathing difficulties
- Facilities for respiratory assistance will always be available.

Your dosages will be calculated according to the indication it is used for and also according to age.

Duration of treatment

- The duration of your treatment will be as short as possible and will not exceed 8 to 12 weeks in case of anxiety, including the withdrawal process
- Extension beyond these periods will not take place without re-evaluation of your situation
- You will be informed when treatment is started, that it will be of limited duration and your dosage will be progressively decreased

- You will be made aware of the possibility of rebound phenomena (see **Special care should be taken with Pharma-Q Diazepam 10 mg/2 ml - Rebound effects**), hereby minimizing anxiety over such symptoms, should they occur while the product is being discontinued.

If you have the impression that the effect of **Pharma-Q Diazepam Injection 10 mg/2 ml** is too strong or too weak, talk to your doctor or pharmacist.

If you are given more Pharma-Q Diazepam Injection 10 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 Diazepam Injection 10 mg/2 ml:

If you are given more than you should be given:

- You may experience coma, slowing down of the central nervous system e.g. decreased heart rate, respiratory depression (abnormally slow or shallow breathing) and cardiovascular depression (problems with the heart)
- Your cardiovascular, respiratory and renal functions will have to be maintained
- Your treatment will be intensive and your symptoms treated and supportive measures will be employed, such as administration of intravenous infusions (drips) to maintain electrolytic balance
- Adequate air passage control will be observed and oxygen may be administered
- Gastric aspiration and lavage (removal of stomach contents) will be performed, followed with 50 g of activated charcoal administered intragastrically (into the stomach)
- Hypotension, if it occurs will be controlled with medicines used for such purposes.

In the event of overdosage, 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 Diazepam Injection 10 mg/2 ml:

If you think that you did not receive a dose of **Pharma-Q Diazepam Injection 10 mg/2 ml**, contact your doctor.

*If you have any further questions on the use of **Pharma-Q Diazepam Injection 10 mg/2 ml**, ask your doctor, nurse, or pharmacist.*

5. POSSIBLE SIDE EFFECTS:

Pharma-Q Diazepam Injection 10 mg/2 ml can have side effects.

Not all side effects reported for **Pharma-Q Diazepam Injection 10 mg/2 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Diazepam Injection 10 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 Diazepam Injection 10 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.

These serious side effects and you may have had an allergic reaction to **Pharma-Q Diazepam Injection 10 mg/2 ml.** You may need urgent medical care or hospitalisation.

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

- abnormally slow or shallow breathing
- 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:

Nervous system disorders:

Frequency unknown: Dizziness, vertigo, light-headedness, headache, contusion, mental depression, slurred speech or difficulty in speaking, difficulty in controlling movements, tremor, forgetfulness and paradoxical excitation (not typical or expected) which may lead to hostility, aggression and a lack of restraint.

Eye disorders:

Frequency unknown: Blurred vision.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: Respiratory depression (abnormally slow or shallow breathing) may occur with high dosage and parenteral administration (by injection).

Gastro-intestinal disorders:

Frequency unknown: Gastro-intestinal disturbances and changes in salivation (e.g. dry mouth).

Hepato-biliary disorders:

Frequency unknown: Jaundice (too much bile in the blood causing a yellow colour to skin, gums, eyes and other tissues).

Renal and urinary disorders:

Frequency unknown: Urinary retention (abnormal holding of urine) or incontinence (not able to control bladder movements).

Reproductive system and breast disorders:

Frequency unknown: Changes in libido (sex drive).

General and administrative site disorders:

Frequency unknown: Blood disorders and low blood pressure may occur with high dosage and parenteral administration (by 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 DIAZEPAM INJECTION 10 mg/2 ml:

Protect from light.

Keep at or below 25 °C.

This product may be refrigerated, but do not freeze.

KEEP OUT OF REACH OF CHILDREN.

7. PRESENTATION OF PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml:

Amber glass ampoules of 10 mg diazepam per 2 ml packed in boxes of 10 or 100.

8. IDENTIFICATION OF PHARMA-Q DIAZEPAM INJECTION 10 mg/2 ml:

A clear, colourless to pale yellow solution in amber ampoules.

9. REGISTRATION NUMBER:

32/2.6/0197

10. NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMA-Q HOLDINGS (PTY) LTD

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