**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:**

**S3**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** injection**.**

**Please read this leaflet carefully before you are given PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **PHARMA-Q VERAPAMIL INJECTION 5 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.

## 1. WHAT PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml CONTAINS

The active substance is verapamil hydrochloride, each 2 ml contains 5 mg.

The other ingredients are

Hydrochloric acid, nitrogen, sodium chloride, water for injections.

## 2. WHAT PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml IS USED FOR

Verapamil belongs to a group of medicines called calcium channel blockers. It is used to treat abnormal heart rhythms such as an irregular or rapid heart rate, chest pains, like angina and for patients suffering from high blood pressure.

## 3. BEFORE YOU ARE ADMINISTERED PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml

**You should not be administered PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml:**

- If you are hypersensitive (allergic) to verapamil hydrochloride or any of the other ingredients of

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml**.

- If you had suffered, or are currently suffering from heart problems such as heart failure, or the heart condition called Wolff-Parkinson-White syndrome.
- If you have an abnormally slow, fast or irregular heartbeat.
- If you have the sick-sinus syndrome unless a pacemaker is fitted.
- If you are pregnant or breastfeeding.

**Take special care with PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml:**

- If you are currently receiving intravenous beta-blockers, e.g. atenolol, propranolol or digitalis, e.g. digoxin.
- If you have very low blood pressure.
- If you have liver or kidney problems.
- If you have a condition where the nerve to muscle transmission is affected, e.g. myasthenia gravis, Duchenne muscular dystrophy.

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

- You have any other heart problems in addition to the one you are being treated for.
- You need any other medication to treat your abnormal heart rhythm.
- You need to be given an anaesthetic.
- You are taking oral verapamil.

**Pregnancy and breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before receiving this medicine.

The safety of **PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** during pregnancy and lactation has not been established.

**Driving and using machinery:**

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** ~~eg~~ may impair your ability to drive or to operate machinery as it may make you feel dizzy.

**Taking other medicines with PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml:**

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

(This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following:

- Beta-blockers used to treat high blood pressure and heart conditions (these include atenolol, propranolol and metoprolol).
- Any other medicine for high blood pressure or an abnormal heart beat (arrhythmia) such as quinidine, disopyramide, flecainide and digoxin.
- Medicines used to treat ulcers, e.g. cimetidine.
- Medicines used to treat depression anxiety or psychosis, e.g. lithium.
- Carbamazepine, phenytoin or phenobarbitone. These medicines are used as anti-convulsants.
- Rifampicin, used to treat tuberculosis and other types of infection.
- Medicines known as immunosuppressants such as ciclosporin. These are used to prevent organ transplant rejection.
- Inhalation anaesthetics.

## 4. HOW TO RECEIVE PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml

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

You will not be expected to give yourself **PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml**. It will be given to you by a person who is qualified to do so.

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** is given to you by injection into a vein (intravenously). The dose will vary according to your condition which will be decided by the doctor. The doctor or healthcare professional will monitor your blood pressure and ECG (The electrical activity of the heart) throughout your treatment. The usual doses are as follows:

**Adults:**

5 - 10 mg is injected over a period of 30 seconds, followed by a further 5mg, if necessary, after 5 to 10 minutes interval.

**Children:**

Neonates: 0,75 to 1 mg.

Infants: 0,75 to 2 mg.

Children aged 1 to 5 years: 2 to 3 mg.

Children aged 6 to 15 years: 2,5 to 5 mg.

Your doctor will tell you how long your treatment with **PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** will last.

If you have the impression that the effect of **PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** is too strong or too weak, tell your doctor or pharmacist.

**If you have received more PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml than you should:**

Since a healthcare professional will administer this medicine, 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 VERAPAMIL INJECTION 5 mg/2 ml:**

Do not receive a double dose to make up for forgotten individual doses.

## 5. POSSIBLE SIDE EFFECTS

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** can have side effects.

Not all side effects reported for **PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

**PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml** affects the rhythm of the heart, but may also slow down the heart rate and cause a drop in blood pressure in some patients.

The doctor or other healthcare professional will therefore monitor you closely during your treatment.

If you experience any of the following side effects tell your doctor immediately:

- Changes in heart rhythm, chest pains for the first time or chest pains becoming frequent
- Swollen ankles
- Unexpected wheezing, difficulty breathing, swelling of the mouth, lips or tongue, itching or a severe skin rash
- Yellowing of the skin or eyes, a fever or tenderness around the middle. These are signs that your liver may not be functioning as well as usual

Other side effects with verapamil include:

*Frequent:*

Dizziness, flushing, headaches, irregular heartbeat, hypotension, constipation

*Less frequent:*

Nausea, worsening heart failure

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

## 6. STORING AND DISPOSING OF PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml

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 label.

## 7. PRESENTATION OF PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml

Containers containing 100 or 10 x 2 ml ampoules.

## 8. IDENTIFICATION OF PHARMA-Q VERAPAMIL INJECTION 5 mg/2 ml

A clear, colourless or almost colourless solution in 2 ml amber ampoules.

## 9. REGISTRATION NUMBER

29/7.1.4/0666

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMA-Q HOLDINGS (PTY) LTD.

50 Commando Road

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## 11. DATE OF PUBLICATION

22 June 2015