**CLEAN COPY OF THE PROPOSED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS: S4**

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

**Pharma-Q Betamethasone Injection 4 mg/1 ml** solution for injection

**Read all of this leaflet carefully before you are given Pharma-Q Betamethasone Injection 4 mg/1 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 Betamethasone Injection 4 mg/1 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 BETAMETHASONE INJECTION 4 mg/1 ml CONTAINS:

The active substance is betamethasone.

Each 1 ml ampoule contains betamethasone sodium phosphate equivalent to betamethasone 4 mg.

The other ingredients are disodium edetate (dihydrate), nitrogen, sodium hydroxide, sodium metabisulphite, 0,32 % *m/v* as antioxidant per 1 ml, sodium phosphate anhydrous and water for injections.

## 1. WHAT PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml IS USED FOR:

Betamethasone sodium phosphate belongs to a group of medicines called corticosteroids which are sometimes referred to as “steroids”. These medicines may be used to treat many different



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medical conditions, from allergic conditions to inflammatory disorders as well as disorders of the adrenal gland.

The adrenal glands are tiny organs that rest on the top of each kidney. Despite their small size, they play a vital role in the body. These glands produce many hormones that affect our development and growth and our ability to deal with stress. These glands also help to regulate kidney function.

Your doctor may therefore prescribe **Pharma-Q Betamethasone Injection 4 mg/1 ml** for you:

- if you are experiencing disorders of the adrenal gland
- if very stressful conditions (e.g. surgery, shock, severe trauma) are affecting your functioning of the adrenal gland
- if you need symptomatic relief from certain inflammatory conditions which will respond to therapy with this medicine.

## 3. BEFORE YOU ARE GIVEN PHARMA-Q BETAMETHASONE INJECTION4 mg/1 ml:

**You should not be given Pharma-Q Betamethasone Injection 4 mg/1 ml:**

- If you are allergic to betamethasone sodium phosphate, any other corticosteroids or any other ingredients in this medicine (see **WHAT PHARMA-Q BETAMETHASONE INJECTION 4 mg/2 ml CONTAINS**)
- if you have osteoporosis (thinning of the bones which may lead to breaks)
- if you have mental problems
- if you have stomach ulcers
- if you are suspected to have, or do have tuberculosis (bacterial infection
- affecting the lungs)



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- if you are suffering from acute viral infections; including herpes zoster (e.g. shingles-blisters which affect your nerve tracts or chicken pox) or if you have ulcers in the eye caused by the herpes virus
- if you are pregnant or breastfeeding since safety in pregnancy and breast-feeding has not been established (see **Pregnancy and Breastfeeding**).

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

**Special care should be taken with Pharma-Q Betamethasone Injection 4 mg/1 ml:**

- it will not be injected into the spaces surrounding the spinal cord or directly into your eye
- you may get toxic effects if this medicine is withdrawn too quickly, used continuously or used in large doses
- you will not get any vaccination which uses live vaccines, while you are on therapy with this medicine.

**Special care will also be taken if you have:**

- congestive heart failure (weakness of the heart causing accumulation of body fluids)
- high blood pressure
- high blood sugar levels
- fits
- increased pressure inside the eye
- diseases which can spread
- ulcers in the eye due to the herpes virus
- long-term kidney failure
- increased levels of blood toxins

- tuberculosis (bacterial infection affecting the lungs)
- are old.

**Pregnancy and Breastfeeding:**

You should not be given **Pharma-Q Betamethasone Injection 4 mg/1 ml** if you are pregnant or breastfeeding since the safety in pregnancy and breastfeeding has not been established (see **You should not be given Pharma-Q Betamethasone Injection 4 mg/1 ml**). It may affect your unborn baby if high doses are used during 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 Betamethasone Injection 4 mg/1 ml.**

**Driving and using machinery:**

You should avoid potentially hazardous tasks such as driving and operating machinery until you know how **Pharma-Q Betamethasone Injection 4 mg/1 ml** affect you.

**Taking other medicines with Pharma-Q Betamethasone Injection 4 mg/1 ml:**

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

**Pharma-Q Betamethasone Injection 4 mg/1 ml** may interact with these medicines:

- medicines used to treat fits (e.g. barbiturates-medicines used to calm you, carbamazepine, phenytoin, primidone and rifampicin)
- medicines use to replace oestrogen (female hormone)

- medicines used to increase urine production when you have high blood pressure (e.g. furosemide)
- medicines used to treat the heart and certain antibiotics (e.g. amphotericin B)
- medicines used to treat clotting
- medicines used to treat inflammation, as concurrent use may give you stomach ulcers and bleeding
- medicines used to treat high blood pressure or high blood sugar levels
- medicines used to treat pain (e.g. aspirin)
- medicines used to treat muscle weakness
- medicines used to increase growth (growth hormone).

## 4. HOW TO RECEIVE PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml:

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

Always receive **Pharma-Q Betamethasone Injection 4 mg/1 ml** exactly as your doctor has prescribed. You should check with your doctor or pharmacist if you are unsure.

**Pharma-Q Betamethasone Injection 4 mg/1 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 Betamethasone Injection 4 mg/1 ml:**

- you may be given **Pharma-Q Betamethasone Injection 4 mg/1 ml** directly into your vein, directly into your muscle, directly into the joint area, directly into the skin or soft tissue or by a drip system
- your doctor will calculate your correct dosage
- your dosage intervals and how you are given **Pharma-Q Betamethasone Injection 4 mg/1 ml** will be adjusted according to your specific requirements, your individual response and your ability to tolerate this medicine.



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If you have the impression that the effect of **Pharma-Q Betamethasone Injection 4 mg/1 ml** is too strong or too weak, talk to your doctor or pharmacist.

**If you are given more Pharma-Q Betamethasone Injection 4 mg/1 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 Betamethasone Injection 4 mg/1 ml overdose:**

For symptoms see **POSSIBLE SIDE EFFECTS** and **Special care should be taken with Pharma-Q Betamethasone Injection 4 mg/1 ml**.

- your treatment will be aimed at treating your symptoms and medical supportive measures will be taken (e.g. oxygen and ventilation)
- your dosages will be decreased and your treatment will be slowly stopped.

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 Betamethasone Injection 4 mg/1 ml:**

If you think that you did not receive a dose of **Pharma-Q Betamethasone Injection 4 mg/1 ml**, contact your doctor.

If you have any further questions on the use of **Pharma-Q Betamethasone Injection 4 mg/1 ml**, ask your doctor, nurse, or pharmacist.

## 5. POSSIBLE SIDE EFFECTS:

**Pharma-Q Betamethasone Injection 4 mg/1 ml** can have side effects.



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

**Nervous system disorders:**

Mental and nervous disturbances.

**Endocrine disorders:**

Decreased functioning of the adrenal gland (responsible for releasing hormones) may occur during long lasting treatment or on stopping treatment and disorders may be increased by stressful situations.

Growth retardation (slow growth) in children and absence of menstrual cycles in women.

Reversible Cushingoid symptoms (e.g. fat accumulation, round / moon face etc.) may be produced with large doses.

**Immune system disorders:**

More sensitive to all kinds of infection, blood infections, tuberculosis (bacterial infection causing a lung disorder), fungal infections, viral infections and slow wound healing.

**Musculoskeletal, connective tissue and bone disorders:**

Muscle weakness and death of bone tissue due to a decreased blood supply.

**Metabolism and nutrition disorders:**

Electrolyte (salt) disturbances are characterised by high blood pressure and swelling, because of the body retaining more sodium and water and the increase in potassium excretion (removal) may cause decreased potassium levels (these are necessary to control the acid-base balance in the body).

**Eye disorders:**

Changes in the eye including growth of cataract (clouding over of the lens of the eye).

**Hepato-biliary disorders:**

Inflammation (swelling, redness and pain in tissues caused by injury or damage) of the pancreas.

**Vascular disorders:**

Increased pressure inside the head.

**Blood and lymphatic system disorders:**

Increased clotting of the blood may lead to thromboembolic complications (clots forming or moving and blocking the circulation).

**Skin and subcutaneous tissue disorders:**

Excessive sweating and skin softening

Not all side effects reported for **Pharma-Q Betamethasone Injection 4 mg/1 ml** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **Pharma-Q Betamethasone Injection 4 mg/1 ml**, please consult your doctor, pharmacist or other healthcare professional for advice.

## 6. STORING AND DISPOSING OF PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml:

Store at or below 25 °C.

Protect from light.

Keep all medicines out of the reach of children.

## 7. PRESENTATION OF PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml:

Ampoules of 1 ml each, boxes of 10 or 100 x 1 ml ampoules.

## 8. IDENTIFICATION OF PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml:

Clear, colourless liquid in a clear ampoule.

## 9. REGISTRATION NUMBER:

32/21.5.1/0338



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## 10. NAME AND ADDRESS OF THE REGISTRATION HOLDER:

PHARMA-Q HOLDINGS (PTY) LTD

50 Commando Road

Industria West, 2093

Johannesburg

South Africa

## 11. DATE OF PUBLICATION:

Original date of registration: 7 May 2002

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