

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****PHARMA-Q BETAMETHASONE INJECTION 4 mg/1 ml****solution for injection****Betamethasone sodium phosphate****Sugar free**

**Read all of this leaflet carefully before you are given PHARMA-Q
BETAMETHASONE INJECTION**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What PHARMA-Q BETAMETHASONE INJECTION is and what it is used for
2. What you need to know before you are given PHARMA-Q BETAMETHASONE INJECTION
3. How PHARMA-Q BETAMETHASONE INJECTION will be administered
4. Possible side effects
5. How to store PHARMA-Q BETAMETHASONE INJECTION
6. Contents of the pack and other information

1. What PHARMA-Q BETAMETHASONE INJECTION is and what it 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 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 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.

2. What you need to know before you are given PHARMA-Q BETAMETHASONE INJECTION

PHARMA-Q BETAMETHASONE INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to betamethasone sodium phosphate, any other corticosteroids, or any of the other ingredients of PHARMA-Q BETAMETHASONE INJECTION (listed in section 6).
- If you are hypersensitive (allergic) any other corticosteroids
- if you have osteoporosis (thinning of the bones which may lead to breaks)
- if you have mental problems
- if you have stomach ulcers, inflamed bulging pouches in your digestive tract, called diverticulitis, if you had recent intestinal to connect certain sections of your intestines (anastomosis)
- if you have a tendency to form blood clots
- if you are suspected to have, or do have tuberculosis (bacterial infection affecting the lungs)
- 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).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Special care should be taken with PHARMA-Q BETAMETHASONE INJECTION

- If you have ever had severe depression or manic depression (bipolar disorder).
This includes having had depression before while using steroid medicines like PHARMA-Q BETAMETHASONE INJECTION or other mental illnesses
- If any of your close family has had these illnesses
- If you have or have ever had tuberculosis (TB)

- If you have epilepsy (fits),
- If you have hypertension (high blood pressure), stomach or duodenal ulcers or diverticulitis (inflammation of the bowel)
- If you have a herpes infection of the eye
- If you have osteoporosis (thinning of the bones). Post-menopausal women are particularly at risk of this
- If you or any of your family have ever had glaucoma (raised eye pressure)
- If you have or recently had a heart disease
- If you have had a stroke or if there is a history of stroke in your family
- If you have recently had a head injury
- If you have just been or are about to be immunised
- If you have recently been in contact with someone who has chickenpox, shingles or measles or recently had chickenpox, shingles, or measles yourself.
This product may make chickenpox, shingles, or measles much worse
- If you or any of your family are diabetic
- If you have an underactive thyroid gland
- If you have myasthenia gravis (a disease which causes muscle weakness)
- If you have liver disease
- If you have an infection
- If you experience blurred vision or other visual disturbances
- If you have pheochromocytoma (a tumour of the adrenal gland)
- If you are an elderly person

Tell your doctor or health care provider before being given the injection

If you have existing or previous history of mental problems while receiving PHARMA-Q BETAMETHASONE INJECTION.

Mental health problems can happen while using steroids like PHARMA-Q BETAMETHASONE INJECTION.

- These illnesses can be serious
- Usually, they start within a few days or weeks of starting the medicine
- They are more likely to happen at high doses
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do occur, they may need treatment.

Talk to a doctor if you (or someone who is using this medicine), shows any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Tell your doctor immediately if you suspect you may have come into contact with a person who has chickenpox, shingles or measles. You should avoid contact with anyone who has either chickenpox, shingles or measles, as it could be extremely serious if you caught any of these from them.

Children

Caution is advised in children as they are more susceptible to systemic toxicity from betamethasone.

Other medicines and PHARMA-Q BETAMETHASONE INJECTION

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

PHARMA-Q BETAMETHASONE INJECTION may interact with certain medicines.

In particular, tell your doctor if you are taking any of the following 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
- Insulin, oral antidiabetic medicine or water tablets (diuretics)
- Medicines used to treat pain (salicylates e.g., aspirin)
- Medicines used to treat muscle weakness
- Medicines used to increase growth (growth hormone)
- Fluoroquinolones (used for some infections)
- Quetiapine (improves symptoms of some mental illnesses)
- Tretinoin (used for skin problems such as bad acne)

PHARMA-Q BETAMETHASONE INJECTION may also affect the results of laboratory tests.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before receiving PHARMA-Q BETAMETHASONE INJECTION.

You should not be given PHARMA-Q BETAMETHASONE INJECTION if you are pregnant or breastfeeding since the safety in pregnancy and breastfeeding has not been established.

It may affect your unborn baby if high doses are used during pregnancy.

Driving and using machines

It is not always possible to predict to what extent PHARMA-Q BETAMETHASONE INJECTION may interfere with the daily activities of a patient.

You should avoid potentially hazardous tasks such as driving and operating machinery until you know how PHARMA-Q BETAMETHASONE INJECTION affects you.

3. How PHARMA-Q BETAMETHASONE INJECTION will be administered

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

You will not be expected to give PHARMA-Q BETAMETHASONE INJECTION to yourself.

PHARMA-Q BETAMETHASONE INJECTION will be given to you by a person who is qualified to do so in a hospital setting.

Your doctor will choose the dose that is right for you.

- You may be given PHARMA-Q BETAMETHASONE INJECTION 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 will be adjusted according to your specific requirements, your individual response, and your ability to tolerate this medicine.

Your doctor will tell you how long your treatment with PHARMA-Q BETAMETHASONE INJECTION will last. If you have the impression that the effect of PHARMA-Q BETAMETHASONE INJECTION is too strong or too weak, talk to your doctor or pharmacist.

If you receive more PHARMA-Q BETAMETHASONE INJECTION than you should:

Since a health care provider will administer PHARMA-Q BETAMETHASONE INJECTION, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

PHARMA-Q BETAMETHASONE INJECTION overdose:

- Your treatment will be aimed at treating your symptoms and medical supportive measures will be taken
- Your dosages will be decreased, and your treatment will be slowly stopped.

If you think you forgot to receive a dose of PHARMA-Q BETAMETHASONE INJECTION

Since a health care provider will administer PHARMA-Q BETAMETHASONE INJECTION, it is unlikely that the dose will be missed

4. Possible side effects

PHARMA-Q BETAMETHASONE INJECTION can have side effects.

Not all side effects reported for PHARMA-Q BETAMETHASONE INJECTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PHARMA-Q BETAMETHASONE INJECTION, please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop using PHARMA-Q BETAMETHASONE 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,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PHARMA-Q BETAMETHASONE INJECTION. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Mental and nervous disturbances,
- If you have recently had a heart attack, betamethasone can sometimes cause a serious complication of the heart, whereby the tissues can become affected by tears or breaks,
- Symptoms of severe pain in your stomach, nausea and vomiting, diarrhoea, fever, loss of appetite and yellowing of your skin (jaundice). These could be a sign of acute pancreatitis.

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

Tell your doctor if you notice any of the following:

Frequent

- Feeling depressed, including thinking about suicide,
- Feeling good (mania) or moods that go up and down,
- Feeling, seeing, or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Frequency unknown

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

wound healing,

- Increased clotting of the blood may lead to thromboembolic complications (clots forming or moving and blocking the circulation),
- 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,
- 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),
- Changes in blood sugar, salt or protein levels, extra hair growth and/or weight gain, increased sweating or increase in appetite,
- Reversible Cushingoid symptoms (e.g., fat accumulation, round/moon face etc.) may be produced with large doses,
- Wasting of muscles, thinning of the bones (osteoporosis) or fractures,
- Changes in the eye including growth of cataract (clouding over of the lens of the eye),
- Worsening of viral or fungal diseases, thinning of the cornea or sclera (the outer membrane of the eye) or other eye problems (which may cause headaches or blurred vision),
- Increased pressure inside the head,
- Heart failure, heart rupture or tear after a recent heart attack,
- Mouth and/or stomach ulcers, oesophageal ulcers (which may bleed),
- Heartburn or indigestion, hiccups, nausea, bloating of the abdomen, thrush in the mouth or throat,

- Bruising, poor wound healing, abscesses, acne, rashes, thinning of the skin, prominent veins, Stevens-Johnson's syndrome, excessive sweating, and skin softening,
- Muscle weakness and death of bone tissue due to a decreased blood supply, tearing of tendons.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of PHARMA-Q BETAMETHASONE INJECTION.

5. How to store PHARMA-Q BETAMETHASONE INJECTION

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Protect from light

6. Contents of the pack and other information

What PHARMA-Q BETAMETHASONE INJECTION contains

- The active substance is betamethasone sodium phosphate.

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, water for injections.

What PHARMA-Q BETAMETHASONE INJECTION looks like and contents of the pack

Clear, colourless liquid in a 1 ml clear ampoule.

Ampoules of 1 ml each. Pack size: boxes of 10 or 100 x 1 ml ampoules.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (Pty) Ltd

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Access to the corresponding Professional Information

TBC