

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****Betamethasone Pharma-Q Injection 4 mg/1 ml solution for injection****Betamethasone****Sugar free**

Read all of this leaflet carefully before you are given Betamethasone Pharma-Q 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.
- Betamethasone Pharma-Q 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.

What is in this leaflet

1. What Betamethasone Pharma-Q Injection 4 mg/1 ml is and what it is used for
2. What you need to know before you are given Betamethasone Pharma-Q Injection 4 mg/1 ml
3. How to receive Betamethasone Pharma-Q Injection 4 mg/1 ml
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1. What Betamethasone Pharma-Q Injection 4 mg/1 ml is and what it is used for

Betamethasone Pharma-Q Injection 4 mg/1 ml contains betamethasone sodium phosphate. 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 Betamethasone Pharma-Q 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.

2. What you need to know before you receive Betamethasone Pharma-Q Injection 4 mg/1 ml

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

- if you are hypersensitive (allergic) to betamethasone sodium phosphate, any other corticosteroids or any of the other ingredients of Betamethasone Pharma-Q Injection 4 mg/1 ml (listed in section 6).
- if you have been told by your doctor that you have a serious fungal infection (systemic fungal infection).

- 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).
- 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 need to go for a live vaccination or have just been vaccinated with one.
- if you are pregnant or breastfeeding since safety in pregnancy and breast-feeding has not been established (see Pregnancy and Breastfeeding).

Warnings and precautions

Betamethasone Pharma-Q Injection 4 mg/1 ml will not be injected into the spaces surrounding the spinal cord or directly into your eye.

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

- If you have recently had a heart attack.
- If you have an underactive thyroid gland (hypothyroidism).
- If you have myasthenia gravis (a disease which causes muscle weakness).
- If you have or suspect that you may have an infection or any infective diseases.
- If you have recently been in contact with someone who has chickenpox, shingles, or measles, or recently had, or have chickenpox, shingles, or measles, yourself. You should consult your doctor if you suspect any of these.
- If you have been receiving this medicine or any other corticosteroids repeatedly for a long period of time.
- If you have been receiving high doses of this medicine or other corticosteroids or repeatedly receiving this medicine in the evenings.

- If you experience any trauma or will be going for a surgical procedure while taking this medicine.
- If you are post-menopausal.
- If you have high blood pressure or other heart problems.
- If you have diabetes mellitus or someone in your family has diabetes.
- If you have a history of tuberculosis (TB).
- If you have an eye infection or suffer from increased pressure in your eye (glaucoma) (or a family history of glaucoma), blurred vision or other visual disturbances.
- If you have ever experienced muscle weakness after taking/receiving a corticosteroid, such as Betamethasone Pharma-Q Injection 4 mg/1 ml.
- If you have liver failure.
- If you have kidney problems.
- If you suffer from seizures (fits).
- If you are elderly.
- If you suffer from inflammatory illnesses, sores, infections, or blockage of the digestive tract (diverticulitis).
- If you have suffered from clotting disorders.
- If you show any signs of mental health changes/problems, talk to your doctor. This is particularly important if you are depressed or might be thinking about suicide. Mental health problems, which can be serious, can occur while using this medicine and they might need treatment.
- If you have a tumour of the adrenal gland (pheochromocytoma).
- If you are taking potassium containing supplements.
- If your diet consists of a high salt intake.
- Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and

shortness of breath. Your healthcare provider will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Children and adolescents

Caution is advised when giving this medicine to a child as they may experience more severe side effects.

Betamethasone Pharma-Q Injection 4 mg/1 ml may cause growth retardation in infancy, childhood and adolescence, which may be irreversible.

Other medicines and Betamethasone Pharma-Q Injection 4 mg/1 ml

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

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

- Anticholinesterase medicines, used in the treatment of myasthenia gravis, as the effect of these medicines may be reduced by Betamethasone Pharma-Q Injection 4 mg/1 ml.
- Phenobarbitone, phenytoin, carbamazepine, primidone, medicines used to treat epilepsy may result in Betamethasone Pharma-Q Injection 4 mg/1 ml being less effective.
- Aminoglutethimide used to treat certain patients with Cushing's syndrome and some types of cancer, may reduce the effectiveness of Betamethasone Pharma-Q Injection 4 mg/1 ml.
- Rifampicin and rifabutin, medicines used to treat tuberculosis (TB) may result in Betamethasone Pharma-Q Injection 4 mg/1 ml being less effective.
- Ephedrine, a medicine in cold and flu medicine may result in Betamethasone Pharma-Q Injection 4 mg/1 ml being less effective.
- The effects of medicines used to treat hypertension including water tablets (diuretics), may be reduced.
- Antidiabetic medicines including insulin may not be as effective.

- Warfarin and aspirin, used to prevent clotting of your blood.
- Theophylline, used to treat lung conditions.
- Carbenoxolone, a medicine used to treat ulcers in your digestive tract.
- Amphotericin B, a medicine used to treat fungal infections.
- Cardiac glycosides (e.g. digoxin), medicines used to treat heart conditions.
- Oral contraceptives, used to prevent pregnancy.
- Cobicistat and ritonavir, medicines used to treat HIV.
- Mifepristone, a medicine used to protect the digestive tract, will result in a reduced effect of Betamethasone Pharma-Q Injection 4 mg/1 ml for 3 to 4 days after taking mifepristone.
- Somatropin, a medicine used to treat growth failure children, may not be effective.
- Non-steroidal Anti-inflammatory Drugs (NSAIDs) used to treat inflammatory conditions should be used very cautiously when taken with Betamethasone Pharma-Q Injection 4 mg/1 ml as the risk of stomach bleeding increases.
- Vecuronium, a medicine used as a muscle relaxant, may not be as effective.
- Fluoroquinolones, medicines used to treat bacterial infections, as your risk of tendon ruptures increases.
- Quetiapine, a medicine used to treat mental conditions, may not be as effective.
- Tretinoin, used to treat skin conditions, may not be as effective.

Betamethasone Pharma-Q Injection 4 mg/1 ml Betamethasone Injection may also affect the results of gall-bladder X-ray procedures.

Pregnancy, breastfeeding and fertility

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 Betamethasone Pharma-Q Injection 4 mg/1 ml.

You should not be given Betamethasone Pharma-Q 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 Betamethasone Pharma-Q Injection 4 mg/1 ml). It may affect your unborn baby if high doses are used during pregnancy.

Betamethasone Pharma-Q Injection 4 mg/1 ml contains sodium metabisulphite

This medicine contains sodium metabisulphite as antioxidant; it may less frequently cause severe hypersensitivity reactions and bronchospasm.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, i.e. essentially 'sodium-free'.

Driving and using machines

Betamethasone Pharma-Q Injection 4 mg/1 ml can cause blurred vision and is expected to influence your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent Betamethasone Pharma-Q Injection 4 mg/1 ml may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Betamethasone Pharma-Q Injection 4 mg/1 ml affects them.

3. How to receive Betamethasone Pharma-Q Injection 4 mg/1 ml

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

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

Betamethasone Pharma-Q 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.

Betamethasone Pharma-Q Injection 4 mg/1 ml:

- you may be given Betamethasone Pharma-Q 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 Betamethasone Pharma-Q Injection 4 mg/1 ml will be adjusted according to your specific requirements, your individual response and your ability to tolerate this medicine.

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

If you take more Betamethasone Pharma-Q Injection 4 mg/1 ml than you should

Since a health care provider will administer Betamethasone Pharma-Q Injection 4 mg/1 ml, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take Betamethasone Pharma-Q Injection 4 mg/1 ml

Since a health care provider will administer Betamethasone Pharma-Q Injection 4 mg/1 ml, it is unlikely that the dose will be missed.

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

4. Possible side effects

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

Not all side effects reported for Betamethasone Pharma-Q Injection 4 mg/1 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects

while receiving Betamethasone Pharma-Q Injection 4 mg/1 ml, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving Betamethasone Pharma-Q Injection 4 mg/1 ml and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes, and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

These are all very serious side effects. If you have them, you may have had a serious reaction to Betamethasone Pharma-Q Injection 4 mg/1 ml. 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:

- Swelling that makes the face round (moon face), a hump behind the shoulder (buffalo hump), unwanted male-pattern hair growth on a woman's face, chest and back (hirsutism), weight gain, flushing, and acne, as these are all symptoms of Cushing's syndrome,
- fatigue, trouble sleeping, allergies, weakened immune function, and food cravings, as these as symptoms of hypothalamic-pituitary- adrenal (HPA) axis suppression,
- growth suppression in babies, children and adolescents,
- increased pressure in your eye (glaucoma),
- swelling and fluid build-up near the eyes and brain called papilloedema (this may result

in a throbbing headache which may be worse upon waking up, coughing or sudden movement and patchy vision with blind spots and possible lack of colour vision) (intracranial hypertension),

- cataracts (cloudy window over your eye),
- redness and swelling of the white part of the eye, blurred vision, and tearing as this could be signs of corneal or scleral thinning,
- chest pain that may feel like pressure, difficulty breathing, cold hands and feet after recently having a heart attack as these are signs of myocardial rupture,
- burning pain the chest, nausea (feeling sick), indigestion, bloating, as these may be signs of oesophageal ulceration,
- pain or discomfort in the abdomen, feeling uncomfortably full too soon while eating a meal with black stools (peptic ulcer),
- severe upper stomach pain with nausea or vomiting, as this may be a sign of a swollen pancreas (pancreatitis),
- low blood levels of potassium which can cause muscle weakness, twitching, confusion, light-headedness, or abnormal heart rhythm (hypokalaemic alkalosis),
- death of bone tissue due to lack of blood supply (avascular osteonecrosis), bone and back fractures, death of the tips of the long bones (femur and humerus),
- blocking of a blood vessel by a blood clot dislodged from its site of origin with symptoms such as shortness of breath, chest pain, cough, or fainting (thromboembolism/ thromboembolic complications),
- suicidal thoughts, feeling, seeing, or hearing things which do not exist (hallucinations), and worsening of a psychiatric condition called schizophrenia (psychotic reactions).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Feeling depressed, feeling irritable, feeling anxious, having trouble sleeping or staying asleep,
- having strange and frightening thoughts, changing how you act or having feelings of being alone.

Side effects with an unknown frequency:

- Increased susceptibility and severity of infections, masking of infections, worsening of viral and fungal eye infections,
- repeat of infections such as TB,
- an increase in the number of white cells in the blood, especially during an infection with symptoms such as fever, bleeding, or bruising (leucocytosis),
- menstrual irregularities/ disturbances such as the absence of a menstrual period (amenorrhoea),
- salt and fluid retention with symptoms such as swelling, or inability of the small intestine to completely process the nutrient carbohydrate (a classification that includes sugars and starches) (decreased carbohydrate tolerance),
- high blood sugar levels (hyperglycaemia),
- high blood pressure with symptoms such as flushed face, headache, blurred vision, tiredness, confusion, and difficulty breathing (hypertension),
- swelling of the stomach (abdominal distention), hiccups, discomfort in the stomach, fungal infection (candidiasis), increased appetite,
- impaired wound healing, thinning of skin, increased bruising, spider veins (telangiectasia) stretch marks, acne,
- muscle weakness (myopathy), thinning of bones (osteoporosis), bone fractures, tendon rupture,

- excessive sweating (hyperhidrosis), a general sense of being unwell (malaise),
- nitrogen depletion with symptoms such muscle weakness and wasting, brittle hair and hair loss.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Betamethasone Pharma-Q Injection 4 mg/1 ml.

5. How to store Betamethasone Pharma-Q Injection 4 mg/1 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 or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Betamethasone Pharma-Q 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.

What Betamethasone Pharma-Q Injection 4 mg/1 ml looks like and contents of the pack

Betamethasone Pharma-Q Injection 4 mg/1 ml contains a clear, colourless liquid in a clear ampoule.

Betamethasone Pharma-Q Injection 4 mg/1 ml is supplied in clear glass ampoules of 1 ml each. Pack size: boxes of 10 or 100 x 1 ml ampoules.

Holder of Certificate of Registration

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This leaflet was last revised in

27 March 2026

Registration number

32/21.5.1/0338

Access to the corresponding Professional Information

<https://www.pharmaq.co.za>