APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DEXAMETHASONE 4 mg/1 ml FRESENIUS solution for injection

Dexamethasone phosphate

Sugar free.

Read all of this leaflet carefully before you are given DEXAMETHASONE 4 mg/1 ml FRESENIUS

- 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 DEXAMETHASONE 4 mg/1 ml FRESENIUS is and what it is used for

DEXAMETHASONE 4 mg/1 ml FRESENIUS is used as an anti-inflammatory medicine or in certain conditions to suppress the body's immune response

2. What you need to know before you are given DEXAMETHASONE 4 mg/1 ml FRESENIUS

DEXAMETHASONE 4 mg/1 ml FRESENIUS should not be given to you:

- If you are hypersensitive (allergic) to corticosteroids, dexamethasone, or any of the other ingredients of DEXAMETHASONE 4 mg/1 ml FRESENIUS (listed in section 6)
- if you have an infection that has not been treated effectively with an antibiotic
- if you have a mental or behavioural disorder
- if you have a herpes simplex infection in your eye
- if you have primary glaucoma (increased pressure in the eye)
- if you have osteoporosis
- if you have a stomach ulcer.

Warnings and precautions

Special care should be taken with DEXAMETHASONE 4 mg/1 ml FRESENIUS

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

- if you have a history of allergies to any medicine
- if you have high blood pressure, heart failure or have recently had a heart attack
- if you have or are suspected of having pheochromocytoma (a rare tumour of the adrenal glands). Treatment with DEXAMETHASONE 4 mg/1 ml FRESENIUS may cause pheochromocytoma crisis, which can be fatal. Crisis can occur with the following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs
- if you have problems with your adrenal glands
- if you have tuberculosis or other infections, including fungal infections or infections caused by parasites or worms
- if you have malaria that is affecting your brain
- if you have chickenpox or herpes zoster (shingles), or have been exposed to someone with

chicken pox or herpes zoster

- if you have measles or have been exposed to someone with measles
- if you have problems with your eyes such as eye infection, cataracts, glaucoma, or a family history of glaucoma
- if you have diabetes (high blood sugar) or a family history of diabetes
- if you have epilepsy
- if you've had previous reactions to steroid therapy such as muscle weakness
- if you have existing or previous mental disorders or a family history of such disorders, including depressed mood, suicidal ideation, psychosis, or a previous history of psychosis, or if you previously had a psychotic reaction when treated with steroids
- if you have a disorder called myasthenia gravis, which causes weak muscles
- if you have infection or inflammation in your intestines, or recently had an operation of the intestines
- if you are at high risk of a condition called tumour lysis syndrome, such as patients with fast growing or large tumours, and high sensitivity to cytotoxic medicines used to treat cancer
- if you have decreased function of your thyroid gland
- if you have kidney or liver problems
- if you have osteoporosis, low blood potassium or calcium levels, high sodium levels or fluid retention
- if you are elderly.

Children

If dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed.

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully monitored.

Children are at increased risk of infection. Infections should be treated as an emergency.

Other medicines and DEXAMETHASONE 4 mg/1 ml FRESENIUS

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

Inform your doctor if you are taking any of the following medicines:

- aminoglutethimide (medicine used to treat Cushing's syndrome)
- anticoagulants (medicines for blood thinning)
- barbiturates (medicines to induce sleep and reduce anxiety)
- carbamazepine, phenytoin, and primidone (medicines to control fits/seizures)
- ephedrine (found in certain cold and flu medicines)
- indomethacin (medicine for pain and inflammation)
- live vaccines
- medicines used for pain and inflammation, called non-steroidal anti-inflammatory medicines such as indomethacin or aspirin
- medicines used to treat high blood sugar (diabetes)
- medicines used to treat high blood pressure (hypertension)
- medicines used to treat myasthenia gravis, a disorder which causes weak muscles
- rifabutin or rifampicin (medicines used to treat tuberculosis)
- oral contraceptives
- ritonavir, darunavir, indinavir, lopinavir, saquinavir and efavirenz (medicines to treat symptoms of HIV)
- diuretics (medicines that increase urination to treat high blood pressure)
- certain asthma medicines
- amphotericin B (medicine to treat fungal infections).

Pregnancy and breastfeeding

Pregnancy

DEXAMETHASONE 4 mg/1 ml FRESENIUS readily crosses the placenta. Receiving high doses of DEXAMETHASONE 4 mg/1 ml FRESENIUS during pregnancy can cause a decrease in the function of the fetus' adrenal gland. New-born babies of mothers who received DEXAMETHASONE 4 mg/1 ml FRESENIUS near the end of pregnancy may have low blood sugar levels after birth.

DEXAMETHASONE 4 mg/1 ml FRESENIUS may slow down growth of the unborn child if given repeatedly and for long periods of time during pregnancy.

Breastfeeding

The safety of this medicine in breastfeeding has not been established.

DEXAMETHASONE 4 mg/1 ml FRESENIUS may pass into breast milk. High doses for long periods during breastfeeding may cause a decrease in the function of the infant's adrenal gland.

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 healthcare provider for advice before receiving DEXAMETHASONE 4 mg/1 ml FRESENIUS.

Driving and using machines

Patients should see how DEXAMETHASONE 4 mg/1 ml FRESENIUS affects them and then judge if it is safe to drive or operate machinery.

DEXAMETHASONE 4 mg/1 ml FRESENIUS contains sodium

DEXAMETHASONE 4 mg/1 ml FRESENIUS contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially sodium-free.

3. How to receive DEXAMETHASONE 4 mg/1 ml FRESENIUS

You will not be expected to give yourself DEXAMETHASONE 4 mg/1 ml FRESENIUS. It will be given to you by a person who is qualified to do so.

Only trained medical personnel should administer DEXAMETHASONE 4 mg/1 ml FRESENIUS. The dose will be adjusted depending on your condition.

DEXAMETHASONE 4 mg/1 ml FRESENIUS will be given to you by injection into a vein, muscle, joint, skin or tissue.

If you receive more DEXAMETHASONE 4 mg/1 ml FRESENIUS than you should

Since a healthcare provider will administer DEXAMETHASONE 4 mg/1 ml FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage

If you forget to receive DEXAMETHASONE 4 mg/1 ml FRESENIUS

Since a healthcare provider will administer DEXAMETHASONE 4 mg/1 ml FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

DEXAMETHASONE 4 mg/1 ml FRESENIUS can have side effects.

Not all side effects reported for DEXAMETHASONE 4 mg/1 ml FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving DEXAMETHASONE 4 mg/1 ml FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, stop receiving DEXAMETHASONE 4 mg/1 ml FRESENIUS and tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and 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 DEXAMETHASONE 4 mg/1 ml FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Increased possibility of acquiring an infection and increased time for a wound to heal.
- Increased clotting of the blood and complications if these clots spread and lodge in other organs in your body.
- High doses cause Cushingoid symptoms which consist of a moon-face; hair growth on the face, chest and upper back; a hump on the back; flushing; increased bruising; lines on the skin, and acne.
- Suppression of growth in children and adolescents.
- Loss of calcium and phosphorus may cause osteoporosis, and the bones may break easier. Back pain may signify osteoporosis.
- Sugar levels in the blood may become higher and you may need to increase the amount of medicine or insulin you use if you are a diabetic.
- Increased appetite, weight gain, salt and fluid retention.
- Excess male-like hair growth in woman, typically on the face, chest and back.
- The amount of potassium in the blood may decrease causing swelling and high blood pressure, leading to heart failure.
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment.

- Glaucoma (increased pressure) and cataracts may occur in your eye. Swelling in the eye, thinning of the outside layer of the eye, eye disease, rare instances of blindness.
- Weakness and a decrease in the size of your muscles.
- Cerebral palsy in prematurely born infants (a group of disorders that affect movement and muscle tone or posture).
- The menstrual cycle may be affected in women.
- Sperm count may be affected in men.
- Mental disturbances such as irritability, intense excitement and happiness, depressed mood, suicidal thoughts, delusions, hallucinations, aggravation of schizophrenia, anxiety, sleep disturbances, confusion and memory loss.
- Behavioural disturbances.
- Convulsions (fits), increased pressure inside the skull, headache, a sensation that the world around you is spinning.
- Inflammation of the pancreas.
- Stomach ulcers with possible rupture and bleeding, rupture of the intestines, inflammation of the pancreas, abdominal discomfort, ulcers or infection in the oesophagus, indigestion, nausea, hiccups.
- Excessive sweating, thin fragile skin, impaired wound healing, rash, itching, redness, discolouration or infection of the skin, acne.
- Burning or tingling especially in the perineal area (after injection into a vein).
- A general feeling of discomfort or a lack of well-being.

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

Reporting of side effects

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **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 DEXAMETHASONE 4 mg/1 ml FRESENIUS.

5. How to store DEXAMETHASONE 4 mg/1 ml FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C, protected from light. Unused portions should be disposed of by a healthcare professional

6. Contents of the pack and other information

What DEXAMETHASONE 4 mg/1 ml FRESENIUS contains

The active ingredient in each 1 ml is dexamethasone sodium phosphate equivalent to 4,0 mg dexamethasone phosphate.

The other ingredients are creatinine, sodium citrate dihydrate, sodium hydroxide 10 % (for pH-adjustment), sodium metabisulphite and water for injections.

Contains 0,1 % *m/v* sodium metabisulphite as an antioxidant.

Sugar free.

What DEXAMETHASONE 4 mg/1 ml FRESENIUS looks like and contents of the pack

A clear, colourless to slightly yellowish solution.

10 x 1 ml clear glass ampoules packed in polystyrene containers, and then packed into outer cartons.

Holder of Certificate of Registration

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