## 1.3.2 PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S4**

**DECASONE INJECTION 4 mg/ml solution for injection**

**Dexamethasone**

**Sugar free**

**Each 1 ml injection contains 0,150 mmol Sodium**

**Read all of this leaflet carefully before you are given**

**DECASONE INJECTION 4 mg/ml**

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

**What is in this leaflet**


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


### 1. What DECASONE INJECTION 4 mg/ml is and what it is used for

DECASONE INJECTION 4 mg/ml contains dexamethasone. It belongs to a group of medicines called corticosteroids.

DECASONE INJECTION 4 mg/ml can be used to:

- Reduce inflammation.
- Treat a number of different diseases of the immune system.

DECASONE INJECTION 4 mg/ml is used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with a body weight of at least 40 kg) with difficulty breathing and need of oxygen.

## 2. What you need to know before you are given DECASONE INJECTION 4 mg/ml

**DECASONE INJECTION 4 mg/ml should not be administered to you:**

- if you are hypersensitive (allergic) to dexamethasone or to any of the inactive ingredients (see section 6).
- if you have had any allergic reactions with corticosteroid treatment in the past.
- if you have a lung disease called tuberculosis (TB).
- If you have been diagnosed with Acute Respiratory Distress syndrome (ARDS, a serious lung disease) for 2 weeks.
- If you have an inflammation of a tendon.
- if you have an infection in the eye called ocular herpes simplex.
- if you have raised eye pressure (glaucoma) or there is a family history of glaucoma.
- if you have a mental disorder with or without symptoms of neurosis or stress (such as depression, anxiety or obsessive behaviour). Consult your doctor before receiving DECASONE INJECTION 4 mg/ml.
- if you have an infection that affects the whole body.

- if you have an active stomach (peptic) or intestinal ulcer.
- if you have a bone disorder called osteoporosis where your bones become less dense and are more likely to break.
- if you are to be vaccinated with live virus vaccines.
- if you have infection of joints.
- if you have unstable joints.

**Warnings and precautions**

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

- if you receive large doses of DECASONE INJECTION 4 mg/ml for a long period.
- if you have thinning of the bones (osteoporosis), particularly if you are a female who has been through menopause.
- if you have high blood pressure or heart disease.
- if you have diabetes (high blood sugar) or there is a family history of diabetes.
- if you have a history of tuberculosis (TB).
- if you have ever experienced muscle weakness during treatment with steroid medicines such as DECASONE INJECTION 4 mg/ml.
- if you suffer from epilepsy or seizures.
- if you have a stomach or intestinal ulcer (refer to DECASONE INJECTION 4 mg/ml should not be administered to you).
- if you suffer from migraine headaches.
- if you have any type of infection. DECASONE INJECTION 4 mg/ml may mask the symptoms of an infection. Consult your doctor as soon as possible.
- if you suffer from stunted growth.
- if you have Cushing's Syndrome.
- if you are elderly.

- if you are planning to receive any vaccinations.
- if you have had a head injury.
- if you have had a stroke.
- if you have kidney or liver problems.
- if you suffer from severe kidney impairment. Your dose may need to be adjusted.
- if you have a history of liver disease or consume excessive quantities of alcohol.
- if you, or any member of your family, have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like dexamethasone.
- if you have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, or in case you suffer from haematological malignancy.
- if you have an under-active thyroid.
- if you had amoebiasis in the past (infection specific to tropical countries which causes diarrhoea).
- if you had a herpes infection of the eye (refer to DECASONE INJECTION 4 mg/ml should not be administered to you).
- if you have an eye disease called glaucoma (or a family history of glaucoma) (refer to DECASONE INJECTION 4 mg/ml should not be administered to you).
- if dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed.
- if you have or are suspected of having pheochromocytoma (a rare tumour of the adrenal glands). Treatment with DECASONE INJECTION 4 mg/ml 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.

**Mental health problems while receiving DECASONE INJECTION 4 mg/ml**

Mental health problems can happen while receiving DECASONE INJECTION 4 mg/ml (see POSSIBLE SIDE EFFECTS):

- These illnesses can be serious.
- They usually 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, you (or they) might need treatment.

Tell a doctor if you (or someone receiving this medicine), show any signs of mental health problems.

This is particularly important if you are depressed or might be thinking about suicide.

Mental health problems have occurred when doses are being lowered or stopped.

**Exposure to infections and contagious diseases**

You should avoid any exposure to infectious diseases. If you do not have a definite history of chickenpox, you must avoid any contact with chickenpox (*herpes simplex*), shingles (*herpes zoster*) or measles.

**Children and adolescents**

DECASONE INJECTION 4 mg/ml causes a slow down in growth (growth retardation) in infancy, childhood and adolescence, which may be irreversible.

DECASONE INJECTION 4 mg/ml should not be used routinely in pre-term neonates with respiratory problems.

**Other medicines and DECASONE INJECTION 4 mg/ml**

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

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

- Medicines to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone.
- Medicines used to treat tuberculosis such as rifampicin and rifabutin.
- Ephedrine used to relieve symptoms of a cough and cold.
- Medicines used to treat certain types of cancers such as aminoglutethimide.
- Medicines used to treat diabetes, including insulin.
- Medicines to treat high blood pressure, including diuretics such as thiazides or furosemide (water tablets).
- Medicines used to treat heart disorders such as digoxin.
- Medicines used to prevent blood clotting such as warfarin.
- Medicines that control pain or lower inflammation, such as aspirin or phenylbutazone.
- Acetazolamide used for glaucoma (refer to DECASONE INJECTION 4 mg/ml should not be administered to you).
- Medicine for fungal infection called amphotericin B.
- Medicines for asthma called xanthines or beta$_2$ agonists.
- Medicines for treating sleep disorders and epilepsy such as barbiturates.
- Medicines for treating stomach ulcers such as carbenoxolone.

- Some medicines may increase the effects of DECASONE INJECTION 4 mg/ml and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

**Pregnancy, breastfeeding and fertility**

The safety of DECASONE INJECTION 4 mg/ml during pregnancy and whilst breastfeeding has not been established. If you are receiving DECASONE INJECTION 4 mg/ml you should not breastfeed your baby.

Newborn babies of mothers who received DECASONE INJECTION 4 mg/ml near the end of pregnancy may have low blood sugar levels after birth.

If you are pregnant or breastfeeding, think you may be pregnant or you are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

**Driving and using machines**

It is not always possible to predict to what extent DECASONE INJECTION 4 mg/ml may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DECASONE INJECTION 4 mg/ml affects you (see section 4).

**DECASONE INJECTION 4 mg/ml contains sulphites**

This medicine contains sulphites which may cause severe allergy (hypersensitivity) and difficulty in breathing.

**DECASONE INJECTION 4 mg/ml contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per ml that is to say essentially 'sodium free.'

## 3. How DECASONE INJECTION 4 mg/ml will be administered

DECASONE INJECTION 4 mg/ml is usually administered by a doctor.

It will be given as an injection into a muscle or under your skin. It can also be given as an injection into a vein. The dose depends on your condition.

Your doctor will decide on the correct dose for you.

If you have the impression that the effect of DECASONE INJECTION 4 mg/ml is too strong or too weak, tell your doctor or pharmacist.

It is unlikely that you need DECASONE INJECTION 4 mg/ml for more than a week or two, unless you receive it for treatment of arthritic joints. If treatment needs to continue you may be given tablets rather than an injection.

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

**If you receive more DECASONE INJECTION 4 mg/ml than you should**

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

**If you forget to receive DECASONE INJECTION 4 mg/ml**

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

Since a healthcare provider will administer DECASONE INJECTION 4 mg/ml, it is unlikely that a dose will be missed.

**If you stop receiving DECASONE INJECTION 4 mg/ml**

If you need to stop this treatment, follow your doctor's advice. The doctor may tell you to lower the amount of medicine you are having gradually until you stop having it altogether. If you stop having this medicine too quickly, your condition may get worse. Withdrawal symptoms may include fever, pain in your muscles and joints, inflammation of the lining of the nose, eye discomfort (conjunctivitis), painful itchy skin lumps, loss of weight and feeling or being sick.

## 4. POSSIBLE SIDE EFFECTS

DECASONE INJECTION 4 mg/ml can have side effects.

Not all side effects reported for DECASONE INJECTION 4 mg/ml are included in this leaflet. Should your general health worsen while receiving DECASONE INJECTION 4 mg/ml **,** please consult your healthcare provider for advice.

If any of the following happens, stop receiving DECASONE INJECTION 4 mg/ml 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,
- severe infection and/or fever which makes you feel ill,

- blood clots causing loss of blood supply to a part of the body; these may include conditions such as deep vein thrombosis (DVT) causing symptoms such as swelling of a leg, or pulmonary embolus (causing shortness of breath and chest pain),
- 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 allergic reaction to DECASONE INJECTION 4 mg/ml. You may need urgent medical attention and/or hospitalisation.

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

- blood in your stools (black, tarry stools),
- vomit any blood or dark particles that look like coffee grounds,
- yellowing of the skin and eyes, also called jaundice,
- stomach ulcers which may perforate or bleed,
- blood clots,
- heart failure,
- fits or epilepsy may become worse,
- experiencing delusions (false ideas or beliefs) or hallucinations (seeing, hearing or feeling things that are not real),
- depression including thinking about suicide,
- loss of vision.

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:*

- stomach problems: having more of an appetite than usual,
- moods that go up and down,
- feeling high (mania),
- changing how you act (behavioural disturbances),
- having or showing a tendency to be easily annoyed (irritability),

*Less frequent side effects*

- Infections: fungal and viral infections, tuberculosis,
- impaired tissue repair and immune function can lead to delayed wound healing,
- stomach problems: indigestion,
- inflamed pancreas: this may cause severe pain in the back or stomach,
- problems with salts in your blood such as too much sodium or low potassium or calcium. You may experience swelling of your limbs (water retention),
- heart and blood problems: high blood pressure,
- bone problems: thinning of the bones (osteoporosis) with an increased risk of fractures, bone disease, damaged tendons,
- skin problems: sweating more than usual, thinning of the skin, increase bruising, acne,
- eye problems: increased pressure in the eye including glaucoma, eye disorders such as cataracts, swelling of the eye,
- hormone problems: irregular or missing periods, stunted growth in children and teenagers, swelling of the face (called a ‘cushingoid’ or ‘moon’ face), it may affect your diabetes and you may notice you start needing higher doses of the medicine

you take for diabetes, your body may not be able to respond normally to severe stress such as accidents, surgery or illness, growth of extra body hair (particularly in women),

- nervous system problems: feeling high (mania), confusion, worsening of mental disorders such as schizophrenia, irritability, anxiousness, sleep disorders, inability to think, remember or reason properly, temporary memory loss,
- muscle problems: muscle weakness or wasting (a decrease in muscle mass), and pain.

*Side effects with an unknown frequency:*

- eye problems: eye infections, blurred vision, loss of vision, cataracts and glaucoma,
- disturbance in your vision, including blurred vision,
- fits, epilepsy or schizophrenia getting worse,
- recurring infections that get worse with each time, recurrence of previous tuberculosis
- stomach problems: nausea, stomach infection, stomach ulcers
- skin problems: wounds that heal slowly, burning, redness and swelling of the skin, increased sweating, acne,
- hormone problems: weight gain,
- slow growth in children or teenagers (the doctor will check for this),
- increase likelihood of bone fractures, tendon rupture
- imbalance in water and salt in the body,
- sleeplessness,
- you feel that you or your surroundings are spinning,

- increase or decrease in pigment of the skin,
- pain, redness or swelling at the injection site (if the injection is into a joint),
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment,
- Increased pressure in the brain with specific eye signs (papilloedema) in children.

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:** https://www.sahpra.org.za/Publications/Index/8

**And/or**

**Aspen Pharmacare:**

**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088

By reporting side effects, you can help provide more information on the safety of DECASONE INJECTION 4 mg/ml.

## 5. How to store DECASONE INJECTION 4 mg/ml

Keep out of the reach and sight of children.

Store at or below 25 °C

Protect from light.

Do not use after the expiry date printed on the label or carton.

Return all unused medicine to your pharmacist.

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

Keep in original packaging until required for use.

## 6. Contents of the pack and other information

**What DECASONE INJECTION 4 mg/ml contains**

The active substance is 4,0 mg of dexamethasone phosphate as the disodium salt.

The other ingredients are creatinine, sodium citrate dihydrate, sodium hydroxide ( for pH-adjustment), sodium metabisulfite, water for injection.

Antioxidant: Sodium metabisulfite 0,1 % *m/v*.

Sugar free.

**What DECASONE INJECTION 4 mg/ml looks like and contents of the pack**

**DECASONE INJECTION 4 mg/ml** is a clear, colourless to slight yellowish solution.

1 ml is packed into a clear Type 1 glass ampoule. 10 ampoules are packed into a polystyrene container together with a leaflet.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 118 088

**This leaflet was last revised in**

29 January 2024

**REGISTRATION NUMBER**

Z/21.5.1/285

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

https://www.sahpra.org.za/pi-pil-repository/

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

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