

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LENISOLONE TABLETS 5 mg

Prednisolone

Contains sugar: Lactose monohydrate 72,00 mg

Read all of this leaflet carefully before you start taking LENISOLONE TABLETS

- 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.
- LENISOLONE TABLETS 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 LENISOLONE TABLETS is and what it is used for
2. What you need to know before you take LENISOLONE TABLETS
3. How to take LENISOLONE TABLETS
4. Possible side effects
5. How to store LENISOLONE TABLETS
6. Contents of the pack and other information

1. What LENISOLONE TABLETS is and what it is used for

LENISOLONE TABLETS belongs to a group of medicines called corticosteroids.

LENISOLONE TABLETS are used in a wide range of inflammatory and auto-immune conditions including:

- blood cell disorders including low red blood and platelet counts,
- allergies, including severe allergic reactions,
- asthma,
- cancer of the white blood cells (leukaemia),
- an immune reaction to eating gluten,
- excess glucose in the blood reducing the ability of the blood cells to absorb and use blood sugar for energy (insulin resistance),
- when the immune system is not functioning as it should be (immunosuppression),
- liver disorders,
- inflammatory bowel disease that causes inflammation in the digestive tract.

2. What you need to know before you take LENISOLONE TABLETS

Do not take LENISOLONE TABLETS:

- if you are hypersensitive (allergic) to prednisolone or any of the other ingredients of LENISOLONE TABLETS (listed in section 6).
- if you have ulcers in the intestines (peptic ulcers).
- if you have weakened bones (osteoporosis).
- if you have a mental illness (psychoses).
- if you have active tuberculosis (TB) or if your doctor suspects you have inactive TB.

- if you currently have an infection including a viral infection such as shingles and/or an eye infection.
- if you are being vaccinated with a live vaccine.

Warnings and precautions

Take special care with LENISOLONE TABLETS:

- if you have any of the following conditions your doctor will need to examine you regularly:
 - High blood pressure, as LENISOLONE TABLETS can increase your blood pressure, you may need more frequent blood pressure checks. You may need to limit your intake of salt and your doctor might need to prescribe a blood pressure lowering supplement.
 - Congestive heart failure (fluid build-up within the heart which causes it to pump inefficiently).
 - Diabetes mellitus (high levels of sugar in the blood) or in those with a family history of diabetes.
 - Kidney problems.
 - Liver problems.
 - Menopause, post menopause (the effect of LENISOLONE TABLETS may be reduced).
 - Severe affective disorders, particularly psychoses, (emotional and mental instability) may get worse if you are taking LENISOLONE TABLETS.
 - Epilepsy and/or seizures, as in some cases taking LENISOLONE TABLETS may aggravate your condition.
 - Previous muscle weakness associated with steroid treatment, as LENISOLONE TABLETS may result in further muscle weakness.

- Myasthenia gravis (characterised by weakness and rapid fatigue of the muscles under your voluntary control).
- Blood clotting (thromboembolic) disorders.
- if you are taking a high dose of LENISOLONE TABLETS you may experience a slower heart rate than normal (bradycardia), and your doctor may need to advise you on stopping your treatment.
- if you undertake increased or strenuous physical activity you may experience unusual muscle pain and deterioration in the fibre of your muscles, your doctor will need to examine you and review your dosage of LENISOLONE TABLETS regularly.
- if you have end stage kidney failure you are at increased risk of calciphylaxis (a serious, uncommon disease), in which calcium accumulates in small blood vessels of the fat and skin tissues which may cause blood clots and painful skin ulcers and lead to infection.
- if you suddenly stop treatment, increase, or reduce your dose of LENISOLONE TABLETS, this may cause acute adrenal insufficiency (you may experience muscle and joint pain, shortness of breath, nausea and vomiting, fever, low blood pressure, dehydration) requiring prompt, emergency medical treatment.
- if you have an infection the symptoms may be masked (covered up) while you are taking LENISOLONE TABLETS and new infections may appear. Tell your doctor if you feel feverish as this may be a sign of a new infection or an existing infection may be worse.
- if LENISOLONE TABLETS has been prescribed to you, you should take care not to come into contact with someone who has chickenpox or measles. You should seek immediate medical advice if you are exposed to either chickenpox or measles.
- if you need to be vaccinated, as certain vaccines should not be administered during certain treatments with LENISOLONE TABLETS, you should wait 3 months after stopping treatment with LENISOLONE TABLETS before being vaccinated.

- if your treatment with LENISOLONE TABLETS is long term, this may cause problems with your eyes, including blurred vision and you may need to be referred to an ophthalmologist.
- if you have glaucoma (a condition of the eye that affects your vision) or a history of glaucoma or a history of glaucoma in your family.
- if you have a hormone disorder which can cause symptoms including gaining weight very quickly, especially on the trunk and face, thinning of the skin and sweating (Cushing's disease), you should avoid taking LENISOLONE TABLETS as your symptoms may get worse.
- if you stop taking LENISOLONE TABLETS this could result in raised intracranial pressure which may cause headaches, blurred vision, vomiting, changes in your behaviour, weakness, or problems with moving or talking, feeling less alert than normal, lack of energy or sleepiness.
- if you have impaired kidney function and/or scleroderma (also known as systemic sclerosis, an autoimmune disorder) because daily doses of 15 mg or more may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and decreased urine production. Your doctor may advise that you have your blood pressure and urine regularly checked.
- if you have an under active thyroid gland which can cause tiredness and weight gain.
- if you are elderly, your doctor will examine you regularly to avoid life threatening reactions from some of the common side effects of LENISOLONE TABLETS, such as osteoporosis (weakened, fragile bones) high blood pressure, diabetes, increased risk of infections and thinning of the skin.

- if you have ever had severe depression or manic-depression. This includes having had depression before or whilst taking steroid medicines such as LENISOLONE TABLETS or if any of your close family has had these illnesses.
- if you (or someone taking this medicine) show any signs of mental health 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 taking this medicine and they might need treatment.

Children and adolescents

LENISOLONE TABLETS may cause growth retardation in infancy, childhood and adolescence, which may be irreversible.

Other medicines and LENISOLONE TABLETS

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

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

- Carbamazepine, phenobarbital, phenytoin and primidone, used for the treatment of epilepsy (fits) as well as the use of barbiturates (sedatives) may result in LENISOLONE TABLETS being less effective.
- Aminoglutethimide, used to treat certain patients with Cushing's syndrome and some types of cancer.
- Antacids, that are used to neutralise stomach acidity and is used to relieve heartburn, indigestion, or an upset stomach.
- Rifampicin or isoniazid, used for the treatment of tuberculosis (TB).

- Erythromycin used to treat bacterial infections such as respiratory tract infections including bronchitis and pneumonia.
- Warfarin or other anticoagulant medicines used to thin the blood.
- Insulin and other medicines used to treat diabetes, as your doctor may need to adjust the dose.
- Antifungal medicines such as amphotericin, which may increase the risk of hypokalaemia (low potassium levels), and ketoconazole.
- Antimuscarinics medicines used to treat conditions such as myasthenia gravis (weakness and rapid fatigue of the muscles under your voluntary control), if taken with LENISOLONE TABLETS may cause memory impairment if you are elderly.
- Carbimazole or other antithyroid medicine, increases the clearance of LENISOLONE TABLETS from your system making it less effective.
- Ritonavir, indinavir or other antiviral medicines used to treat HIV.
- Digoxin used to treat heart conditions, if taken with LENISOLONE TABLETS may increase the risk of toxicity (poison) if hypokalaemia (low potassium levels) occurs.
- Ciclosporin, used to reduce pain, swelling and stiffness in rheumatoid arthritis, if taken with LENISOLONE TABLETS may require your doctor to adjust your doses of these medicines.
- Methotrexate (medicine used to treat cancer) if taken together with LENISOLONE TABLETS may result in haematological toxicity (a decrease in bone marrow and blood cells), which may lead to infection, bleeding, or anaemia.
- Oral contraceptives may increase the blood level of LENISOLONE TABLETS resulting in an increased chance of undesirable effects.
- Immunosuppressants, medicines which dampen down the activity of the body's immune system.

- Mifepristone (a medicine used to terminate pregnancy) will result in a reduced effect of LENISOLONE TABLETS for 3 to 4 days after taking mifepristone.
- Aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) such as diclofenac used for treating inflammation and pain, should be used very cautiously as when taken together with LENISOLONE TABLETS your risk of severe stomach problems increases.
- Female sex hormones (oestrogens) taken together with LENISOLONE TABLETS may require dosage adjustments.
- Water tablets (diuretics) taken with LENISOLONE TABLETS may cause excessive loss of potassium in the blood.
- Somatropin (growth hormone) as the growth promoting effect may be inhibited.
- Medicines used to treat breathing difficulties, allergic rhinitis and conjunctivitis, such as salbutamol and terbutaline, as they may result in an increased risk of hypokalaemia (low potassium levels) if taken with high doses.
- Medicines used to treat heart conditions (such as high blood pressure).
- Theophylline, used to treat asthma and chronic obstructive pulmonary disease (COPD).
- Carbenoxolone which is used for ulcers.
- Acetazolamide which is used in the treatment of glaucoma and epilepsy.

LENISOLONE TABLETS with food

Avoid eating liquorice whilst taking LENISOLONE TABLETS.

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 healthcare provider for advice before taking this medicine.

You should avoid taking LENISOLONE TABLETS if you are breastfeeding, as this medicine is excreted into breast milk and may harm your baby.

Driving and using machines

LENISOLONE TABLETS may cause dizziness and visual disturbances which may influence your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent LENISOLONE TABLETS 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 LENISOLONE TABLETS affects you.

LENISOLONE TABLETS contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take LENISOLONE TABLETS

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

Always take LENISOLONE TABLETS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe a specific dose and duration of treatment based on your condition.

Your doctor will tell you how long your treatment with LENISOLONE TABLETS will last. Do not stop treatment early because this may result in undesirable side effects. Your doctor will advise you on a gradual withdrawal of treatment and will also monitor you. If you have the impression that the effect of LENISOLONE TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more LENISOLONE TABLETS than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you take high doses of LENISOLONE TABLETS, you may experience side effects such as psychosis (mental state where thoughts and emotions are impaired), depression, hallucinations (seeing or hearing things which do not exist), cardiac dysrhythmias (abnormal heart rhythm) and Cushing's syndrome (signs are fatty hump between the shoulders, a rounded face and pink or purple stretch marks).

In the event of overdose your doctor may reduce your dosage gradually and slowly withdraw treatment with LENISOLONE TABLETS.

If you forget to take LENISOLONE TABLETS

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

If you stop taking LENISOLONE TABLETS

LENISOLONE TABLETS should not be stopped suddenly. Your doctor will advise you how to stop treatment in a gradual manner. Your doctor will also monitor you during this period.

If treatment is stopped too quickly it can lead to severe problems of the adrenal gland. You may experience 'withdrawal symptoms' which include fever, muscular pain, weakness, joint pain, runny nose, an eye infection (conjunctivitis), painful itchy skin lumps, loss of weight, mental changes, mood changes, feeling sick and/or being sick, low blood pressure, feeling faint, headache, dizziness and reappearance of your disease symptoms. You may also experience swelling of the nerves in the eyes due to increase in pressure in and around the brain.

4. Possible side effects

LENISOLONE TABLETS can have side effects.

Not all side effects reported for LENISOLONE TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LENISOLONE TABLETS, please consult your healthcare provider for advice.

If any of the following happens, stop taking LENISOLONE TABLETS 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to LENISOLONE TABLETS. 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:

- Failure of the heart to pump correctly (heart failure). Symptoms include chest pain, shortness of breath (dyspnoea), fainting, swelling in the legs or feet,
- slow heart rate (bradycardia), high blood pressure (hypertension),
- feeling severely depressed, including thinking about suicide,
- seeing and hearing things that are not real or personality changes,
- fits (convulsions),
- severe headaches, nausea and vomiting and loss of vision, as these may be a sign of raised pressure in the brain,
- numbness, weakness or tingling, nausea (stroke-like symptoms),
- vision loss,
- blockage of blood vessels by blood clots (thromboembolism),

- ulcers in the stomach, intestines, or food pipe, which show symptoms such as severe stomach pain, vomiting blood, or blood in stool,
- severe upper stomach pain with nausea or vomiting, as this may be a sign of a swollen pancreas (pancreatitis),
- deep, very painful lumps that develop into open sores that do not heal, purple net-like patterns on the skin (calciophylaxis),
- sudden high blood pressure, kidney failure and decreased urine production, particularly if you have sclerosis (scleroderma renal crisis),
- coughing for a few weeks, coughing up blood or mucous, unintentional weight gain, tiredness, night sweats (tuberculosis),
- sudden onset of fever, low body temperature, shaking, chills, confusion, difficulty breathing, may be signs that your body is fighting a severe infection (sepsis).

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:

- Changes in behaviour, mood swings, difficulty concentrating, confusion, sleep disturbances, memory loss,
- feeling irritable, anxious, restless or nervous,
- indigestion.

Side effects with an unknown frequency:

- A feeling of intense excitement and happiness,
- a feeling of whirling and loss of balance (vertigo),
- eye problems such as blurred vision as this may be an indication of the development of increased pressure in the eye (glaucoma) or a cataract (clouding of the lens of the

eyes); or changes in the way you see things due to a fluid collection within your eye; or bulging or protruding of the eyes; or sudden appearance of many floaters,

- redness or blisters on an affected area of skin, peeling or cracking skin, itching, stinging or burning sensation on the skin, abnormal vaginal discharge (fungal infection),
- dry mouth, difficulty swallowing, white lesions in your food pipe (candidiasis),
- fever, bleeding, bruising, sweating, loss of weight without trying (leucocytosis),
- a hormone imbalance causing Cushing's syndrome. Typical symptoms include a round face (moon face) and fatty hump between the shoulders (buffalo hump),
- general feeling of weakness, stomach pain, poor weight gain, headache (suppression of the adrenal gland),
- signs of diabetes, such as increased thirst, increased need to urinate, dry mouth, blurry vision, slow healing of cuts or sores,
- if you are diabetic, you may notice that you may need changes in your diabetes medicine (oral or insulin),
- acid-base imbalance in the blood due to low potassium levels. Symptoms include confusion, hand tremor, light-headedness, muscle twitches, nausea or vomiting,
- swelling (water and salt retention),
- muscle spasm and/or weakness, twitching, convulsions (altered levels of electrolytes in the blood),
- loss of muscle mass,
- weight gain, obesity, increased appetite,
- feeling sick (nausea), stomach pain, diarrhoea,
- high levels of bad cholesterol in the blood,
- increased sweating,
- trouble falling and/or staying asleep (insomnia), dizziness, headache,

- back pain and weakness, loss of sensation or slow reflexes may be a sign of excessive fat build up on or outside the lining of the spine,
- thin fragile skin, excess hair, skin bruises, flushing, stretch marks, spider veins, acne,
- muscle pain or weakness in upper or lower limbs,
- bone problems such as fragile bones or wasting of the bones (osteoporosis),
- breaks in your bones (fractures),
- tendon rupture (when a muscle is torn from the bone at the point of attachment), particularly of the ankle and knee tendons,
- menstrual irregularities such as excessive, delayed or no monthly periods,
- slow healing,
- general sense of being unwell and/or discomfort, tiredness (fatigue).

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/health-products-vigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of LENISOLONE TABLETS.

5. How to store LENISOLONE TABLETS

Store all medicines out of reach of children.

Store at or below 25 °C in airtight containers.

Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 LENISOLONE TABLETS contains

The active substance is 5 mg of prednisolone.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose (102), talc (purified).

Contains sugar: Lactose monohydrate 72,00 mg.

What LENISOLONE TABLETS looks like and contents of the pack

LENISOLONE TABLETS is a white shallow biconvex tablet bisected on one side plain on the other side.

Pack size of 100 and 500 tablets: Packed into white cylindrical polypropylene securitainers together with a package insert. The container is stoppered with a white polyurethane foam insert, capped with a white low density polyethylene cap.

Pack size of 1 000 tablets: Packed into white cylindrical polypropylene securitainers together with a package insert. The container is stoppered with a white polyurethane foam insert, capped with a white low density polyethylene cap.

Or



Packed into white opaque HDPE container with a White opaque HDPE screw closure with IS liner.

Pack size of 5 000 tablets: Packed into amber PVC containers together with a package insert. The container is stoppered with a polyurethane foam insert, capped with a white pilfer proof cap.

Holder of Certificate of Registration

PHARMACARE LIMITED

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G2968 (Act 101/1965)

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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