1.3.2.1 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPELONE 15 mg per 5 ml liquid

Prednisolone

Contains sugar: Sorbitol liquid (70 %) 2,5 g/5 ml,

Contains sugar: Glycerol 0,5 g/5 ml

Contains sweetener: Saccharin sodium 7,5 mg/5 ml

Read all of this leaflet carefully before you start taking ASPELONE

- 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.
- ASPELONE 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 ASPELONE is and what it is used for

ASPELONE belongs to a group of medicines called corticosteroids and is used to provide relief for inflamed areas of the body. Corticosteroids lessen swelling, redness, itching, and allergic reactions.

2. What you need to know before you take ASPELONE

Do not take ASPELONE:

- if you are hypersensitive (allergic) to cortisone-like medicines including prednisolone or any of the other ingredients of ASPELONE (listed in section 6).
- if you have a fungal infection throughout your body.
- if you have a severe infection caused by a virus (such as herpes zoster) or bacteria.
- if you have stomach and/or duodenal ulcers or any other painful stomach conditions.
- if you have osteoporosis.
- if you show any psychotic behaviour or suffer from any mental illnesses.
- if you have active or latent tuberculosis.
- if you had a vaccination without your doctor's approval (specifically a live vaccine).
- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with ASPELONE:

- if you are elderly.
- if you currently have an infectious disease.
- if you have kidney problems.
- if you have 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. The doctor may advise that you have your blood pressure and urine regularly checked.
- if you have any of the following conditions your doctor will need to examine you regularly:
  - High blood pressure, as ASPELONE 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) or recent heart attack.
  - Under functioning thyroid gland (hypothyroidism).
  - Muscle weakness from previous steroid use.
  - Diabetes mellitus (high levels of sugar in the blood) or in those with a family history of diabetes.
  - Liver problems.
  - Severe affective disorders, particularly psychoses, (emotional and mental

instability) may get worse if you are taking ASPELONE (see section 'Do not take ASPELONE').

- Epilepsy and/or seizures, as in some cases taking ASPELONE may aggravate your condition.
- Myasthenia gravis (characterised by weakness and rapid fatigue of the muscles under your voluntary control).

- if you are taking a high dose of ASPELONE, you may experience a slower heart rate than normal (bradycardia), and your doctor may need to advise you on stopping your treatment.
- if you suffer from a tumour of the adrenal gland (Pheochromocytoma).
- if you suddenly stop treatment, increase, or reduce your dose of ASPELONE, 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 ASPELONE 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 ASPELONE 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 your treatment with ASPELONE causes problems with your eyes, including blurred vision, you may need to be referred to an ophthalmologist.
- if you have glaucoma (a condition of the eye that affects your vision).
- 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 ASPELONE as your

symptoms may get worse.

- if you are elderly, your doctor will examine you regularly to avoid life threatening reactions from some of the common side effects of ASPELONE like high blood pressure, diabetes, increased risk of infections and thinning of the skin.
- if you have ever had depression or manic-depression. This includes having had depression before or whilst taking steroid medicines such as ASPELONE or if any of your close family has had these illnesses (see section 'Do not take ASPELONE').
- 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 (see section 'Do not take ASPELONE').
- if you have lesions on your skin as it could be a type of cancer (Kaposi's sarcoma).
- 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.

Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

Children

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

Other medicines and ASPELONE

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:

- Carbamazepine, phenobarbitone, phenytoin and primidone, used for the treatment of epilepsy (fits) as well as the use of barbiturates (sedatives) may result in ASPELONE being less effective.
- Aminoglutethimide, used to treat certain patients with Cushing's syndrome and some types of cancer.
- Rifampicin and rifabutin, 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 (antidiabetic medicines).
- Antifungal medicines such as amphotericin, which may increase the risk of hypokalaemia (low potassium levels), and ketoconazole.
- Antimuscarinics or anticholinesterase medicines used to treat conditions such as myasthenia gravis (weakness and rapid fatigue of the muscles under your voluntary control), if taken with ASPELONE may cause memory impairment if you are elderly.
- Ritonavir, or other antiviral medicines used to treat HIV.
- Ciclosporin, used to reduce pain, swelling and stiffness in rheumatoid arthritis, if taken with ASPELONE may require your doctor to adjust your doses of these medicines.

- Methotrexate (medicine used to treat cancer) if taken together with ASPELONE 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 ASPELONE 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 ASPELONE for 3 to 4 days after taking mifepristone.
- Salicylates, 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 ASPELONE your risk of severe stomach problems increases.
- Salicylates e.g. aspirin may be cleared out of the body faster when taken with prednisolone, as contained in ASPELONE. Prednisolone withdrawal could cause salicylate toxicity.
- Female sex hormones (estrogens) taken together with ASPELONE may require dosage adjustments.
- Water tablets (diuretics e.g. thiazides, furosemide) taken with ASPELONE may cause excessive loss of potassium in the blood (potassium depleting diuretics).
- Somatropin (growth hormone) as the growth promoting effect may be inhibited.
- Medicines used to treat breathing difficulties, allergic rhinitis and conjunctivitis, such as salbutamol, salmeterol, fenoterol, formoterol, bambuterol, ritodrine 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) known as antihypertensives.
- Theophylline, used to treat asthma and chronic obstructive pulmonary disease (COPD) and other medicines like xanthines and b_2 receptor agonists.
- Carbenoxolone which is used for ulcers.
- Acetazolamide which is used in the treatment of glaucoma and epilepsy.
- If low levels of potassium occur due to prednisolone, as contained in ASPELONE, patients on cardiac glycosides (medicine for the heart) may have increased toxicity.
- Ephedrine, used to increase blood pressure, may decrease the effect of prednisolone as contained in ASPELONE.
- The effect of a certain type of x-ray (cholecystographic x-ray media) may be reduced by prednisolone, as contained in ASPELONE.

ASPELONE with food and drink

ASPELONE may be taken with or without food.

Pregnancy and breastfeeding

ASPELONE is contraindicated in pregnancy and lactation (see Do not take ASPELONE).

You should not take ASPELONE if you are pregnant or breastfeeding your baby.

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 ASPELONE.

Driving and using machinery

ASPELONE has no or negligible influence on the ability to drive or operate machinery. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ASPELONE does not adversely affect your ability to do so safely (see section 4).

It is not always possible to predict to what extent ASPELONE 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 ASPELONE affects you (see section 4).

ASPELONE contains sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take ASPELONE.

ASPELONE contains sorbitol and glycerol and may have a laxative effect.

ASPELONE contains propylene glycol

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

ASPELONE contains preservatives sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate

ASPELONE contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate and may cause allergic reactions (possibly delayed).

3. How to take ASPELONE

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

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

The dose of ASPELONE can be different for different users. Follow your doctor's instructions and do not use it for a longer time than your doctor ordered.

The dosage of ASPELONE depends on the condition being treated and your response to therapy.

Adults: The usual dose of ASPELONE is about 3 mg to 60 mg daily in divided doses depending on the underlying condition.

Paediatrics: When prescribing doses for infants and children, one should not only adhere to ratios indicated by age or body weight but should also consider the guidelines followed when prescribing doses in adults.

The usual paediatric daily dose of ASPELONE is 0,5 mg to 2 mg per kg of body weight or 15 to 60 mg per square metre of body surface area in three divided doses.

ASPELONE may be given daily as a single dose after breakfast or as a double dose on alternate days.

You may require higher initial doses, where low doses should be sufficient in less severe situations.

Your doctor will tell you how long your treatment with ASPELONE 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 ASPELONE is too strong or too weak, tell your doctor or pharmacist.

If you take more of ASPELONE 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 forget to take ASPELONE

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

If you have missed a dose of ASPELONE, take the dose that you have missed as soon as you remember.

If you stop taking ASPELONE

ASPELONE should not be stopped suddenly. Only take ASPELONE for the time period indicated by your doctor. In this case, your doctor will advise you to reduce the dose slowly before stopping ASPELONE completely.

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

ASPELONE can have side effects.

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

If any of the following happens, stop taking ASPELONE 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 ASPELONE. 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, fainting, swelling in the legs or feet,
- tear in the heart after a recent heart attack (myocardial rupture),
- slow heart rate (bradycardia),
- feeling severely depressed, including thinking about suicide,
- seeing and hearing things that are not real or personality changes,
- wound healing may be delayed and you may have increased susceptibility to infection (sepsis, tuberculosis, fungal infections and viral infections). The signs

of infection may be masked,

- you may retain water and have resultant swelling (oedema) and an increase in blood pressure (hypertension). This can result in abnormally low levels of potassium in the blood (hypokalaemia) and in extreme cases, heart failure,
- death of bone tissue (can lead to sepsis),
- fits (convulsions),
- severe headaches, nausea and vomiting and loss of vision, as these may be a sign of raised pressure in the brain (benign intra-cranial hypertension),
- blockage of blood vessels by blood clots (embolism and 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 (inflammation of the pancreas),
- 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, tiredness, night sweats (tuberculosis and recurrence of dormant 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),
- a rare type of cancer which can affect both the skin and internal organs (Kaposi's sarcoma),
- 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 (central serous chorioretinopathy); or bulging or protruding of the eyes (exophthalmos); or sudden appearance of many

floaters, thinning of the cornea and sclera of the eyes, swelling of the discs in the eyes (papilloedema),

- increased amount of fat in the upper back and neck (“buffalo hump”), the presence of coarse hair on the face, chest and upper back or abdomen, flushing, increased bruising, stretch marks, acne, osteoporosis (Cushingoid manifestations),
- growth suppression in children may occur.

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:

- Breaks in your bones (fractures),
- increase in appetite,
- bone problems such as fragile bones or wasting of the bones (osteoporosis).

Less frequent side effects:

- Excessive sweating,
- signs of diabetes, such as increased thirst, increased need to urinate, dry mouth, blurry vision, slow healing of cuts or sores,
- mental problems.

Side effects with an unknown frequency:

- Changes in behaviour, worsening of an existing mental illness, mood swings, difficulty concentrating, confusion, sleep disturbances, memory loss,
- dependence,

- indigestion,
- 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),
- general feeling of weakness, stomach pain, poor weight gain, headache (suppression of the adrenal gland),
- if you are diabetic, you may notice that you may need changes in your diabetes medicine (oral or insulin) and your tolerance to carbohydrates may change,
- salt imbalances or water retention in the body,
- low levels of potassium in the blood, which may result in tiredness, confusion, or muscle cramps,
- loss of muscle mass,
- weight gain,
- feeling sick (nausea), stomach pain, diarrhoea, vomiting,
- trouble falling and/or staying asleep (insomnia), dizziness, headache,
- thin delicate skin, unusual marks on the skin or bruising, appearance of stretch marks, acne,
- muscle pain or weakness in upper or lower limbs,
- 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 feeling of being unwell with extreme tiredness (malaise),
- hiccups,

- sensation of spinning (vertigo).

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 ASPELONE.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

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

5. How to store ASPELONE

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Shake the bottle before use and keep it well closed.

Keep in original packaging until required for use.

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 ASPELONE contains

The active substance is prednisolone sodium phosphate equivalent to 15 mg of prednisolone base.

The other ingredients are colour raspberry red (C.I.14720), dipotassium hydrogen phosphate (for pH adjustment), disodium edetate, flavour raspberry, glycerol, potassium dihydrogen phosphate (for pH adjustment), propylene glycol, purified water, saccharin sodium, sodium chloride, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sorbitol liquid.

Preservatives:

Sodium methyl parahydroxybenzoate 0,21 % *m/v*

Sodium propyl parahydroxybenzoate 0,022 % *m/v*

Contains sugar: Sorbitol liquid (70 %) 2,5 g/5 ml, glycerol 0,5 g/5 ml

Contains sweetener: Saccharin sodium 7,5 mg/5 ml

What ASPELONE looks like and contents of the pack

ASPELONE is a clear, pinkish-red liquid, free from foreign particles with a sweet raspberry smell.

100 ml is packed in a round amber glass bottle sealed with a white, tamper evident, expanded polyethylene lined polypropylene screw cap. The bottle is placed in a cardboard unit carton with a leaflet.

50 ml is packed in a round amber glass bottle sealed with a white, tamper evident, expanded polyethylene lined polypropylene screw cap. The bottle is placed in a cardboard unit carton with a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

26 November 2025

Registration number

41/21.5.1/0189

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

Botswana: BOT1302417 S2

Namibia: NS2 11/21.5.1/0007