**SCHEDULING STATUS:** S4

**ADCO-PREDNISOLONE SYRUP, syrup (15 mg / 5 ml)**

**Prednisolone**

**Contains Sugar: 625 mg / 5 ml Invert sugar and**

**625 mg / 5 ml Sorbitol solution (70 %)**

**Contains Sweetener: 10 mg / 5 ml Saccharin Sodium**

**Read all of this leaflet carefully before you start taking (or giving) ADCO-PREDNISOLONE SYRUP.**

- 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.
- ADCO-PREDNISOLONE SYRUP has been prescribed for you, or your child, personally and you should not share your (or your child's) medicine with other people. It may harm them, even if their symptoms are the same as yours (or your child's).

**What is in this leaflet**

1. What ADCO-PREDNISOLONE SYRUP is and what it is used for
2. What you need to know before you take (or give) ADCO-PREDNISOLONE SYRUP
3. How to take (or give) ADCO-PREDNISOLONE SYRUP
4. Possible side effects
5. How to store ADCO-PREDNISOLONE SYRUP
6. Contents of the pack and other information

## 1. What ADCO-PREDNISOLONE SYRUP is and what it is used for

Prednisolone (the active ingredient of ADCO-PREDNISOLONE SYRUP) is a corticosteroid medicine that is mainly used for its anti-inflammatory effects.

ADCO-PREDNISOLONE SYRUP is used to provide relief from symptoms of inflammation that may be caused by a number of different diseases, as determined by your doctor.

## 2. What you need to know before you take (or give) ADCO-PREDNISOLONE SYRUP

**Do not take ADCO-PREDNISOLONE SYRUP (or give to your child):**

- if you are hypersensitive or allergic to prednisolone or other corticosteroids, or to any of the other ingredients in ADCO-PREDNISOLONE SYRUP (listed in section 6).
- if you are pregnant or breastfeeding.
- if you suffer from osteoporosis, inflammation of the gullet or stomach, stomach ulcer or psychological disturbances (mental health problems).
- if you have a fungal, bacterial or viral infection, or if you are suffering from active tuberculosis, unless advised by your doctor.
- if you recently had a vaccination (of a live vaccine) without your doctor's approval. If you are receiving high doses of ADCO- PREDNISOLONE SYRUP, immunisation with a live vaccine should not be undertaken for up to 3 months after you have stopped using ADCO-PREDNISOLONE SYRUP.

**Warnings and precautions**

Take special care with ADCO-PREDNISOLONE SYRUP:

- if you are elderly. If you are elderly, your doctor will monitor you closely while taking ADCO-PREDNISOLONE SYRUP as you may be more likely to experience side effects, like high

blood pressure, diabetes, increased risk of infections and thinning of the skin.

- if you have an infection. While taking ADCO-PREDNISOLONE SYRUP you may become more prone (susceptible) to infection and if you have an infection, the symptoms may be masked (covered up). 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 you have kidney problems like chronic kidney failure and uraemia (retention of waste-products in the urine due to kidney failure).
- if you are taking a high dose of ADCO-PREDNISOLONE SYRUP you may experience a slower heart rate than normal (known as bradycardia). This can also happen at lower doses of ADCO-PREDNISOLONE SYRUP and especially if you have heart or kidney problems, if you are taking other medicine that slows down heart rate or if you have a salt (electrolyte) imbalance (which can be caused by water pills, also known as diuretics, or from excessive vomiting). Your doctor may advise you to stop taking ADCO-PREDNISOLONE SYRUP.
- you should take care not to come into contact with someone who has chickenpox or measles while taking ADCO-PREDNISOLONE SYRUP. Seek immediate medical advice if you are exposed to either chickenpox or measles.
- if you have ever had depression or manic-depression. This includes having had depression before or whilst taking steroid medicines such as ADCO-PREDNISOLONE SYRUP or if any of your close family members have had these illnesses. Mental health problems, which can be serious, can occur while taking ADCO-PREDNISOLONE SYRUP and treatment for this may be needed. If you (or someone taking this medicine) show any signs of mental health problems, talk to your (or their) doctor. This is particularly important if you are depressed or might be thinking about suicide.
- if you experience problems with your eyes or eyesight (vision), including blurred vision,

while taking ADCO-PREDNISOLONE SYRUP. You may need to be referred to an ophthalmologist (eye specialist).

- if you have scleroderma (also known as systemic sclerosis, an autoimmune disorder). Daily doses of 15 mg or more of ADCO-PREDNISOLONE SYRUP may increase the risk of a serious complication called scleroderma renal crisis. Signs of scleroderma renal crisis include increased blood pressure and passing less urine. Your doctor may tell you that you should get your blood pressure and urine checked regularly.
- if you have a condition known as myasthenia gravis (a neuromuscular disorder that causes weakness in the skeletal muscles, which are the muscles your body uses for movement). The medicine you use to control the myasthenia gravis may not work as well if you are also taking ADCO-PREDNISOLONE SYRUP.
- if you have pheochromocytoma (a tumour / cancer of the adrenal gland).

If you have any of the following conditions your doctor will monitor you regularly:

- high blood pressure, as ADCO-PREDNISOLONE SYRUP can increase your blood pressure.
- heart failure or a recent heart attack.
- diabetes mellitus (high levels of sugar in the blood).
- glaucoma (an eye condition where the pressure in your eye is increase which affects your vision).
- epilepsy and/or seizures.
- liver or kidney problems.
- hypothyroidism (underactive thyroid, where the thyroid gland can’t make enough thyroid hormone).

ADCO-PREDNISOLONE SYRUP may aggravate (worsen) the above conditions.

Furthermore, if you have been using ADCO-PREDNISOLONE SYRUP for a long time, your doctor should assess you on a regular basis for high blood pressure, low potassium levels, presence of abnormal amounts of glucose in the urine, discomfort in the stomach and mental health problems. Your doctor may advise you to take additional potassium supplements and to reduce your dietary intake of sodium.

ADCO-PREDNISOLONE SYRUP may also affect your response to treatment for high blood pressure and diabetes, as well as medicines known as anticoagulants (used to thin the blood and prevent clots). Your doctor will monitor you closely.

Don't stop taking (or giving) ADCO-PREDNISOLONE SYRUP unless your doctor tells you (or without talking to your doctor); you may need to lower the dose gradually. This is because if treatment is stopped too quickly it can lead to "withdrawal" symptoms due to severe problems of the adrenal gland. **This can be serious and even cause death** (see section 3: "If you stop taking (or giving) ADCO-PREDNISOLONE SYRUP".)

**Children and adolescents**

Infants, children and teenagers taking ADCO-PREDNISOLONE SYRUP may grow slower than normal. If you think this is happening to a child, tell your doctor.

**Other medicines and ADCO-PREDNISOLONE SYRUP**

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

*Vaccinations*

Before taking ADCO-PREDNISOLONE SYRUP (or giving it to your child), tell your doctor if you (or you child) have been recently vaccinated. If you are going to have any injections or vaccinations, tell your doctor, pharmacist or nurse you are taking ADCO-PREDNISOLONE SYRUP. Some vaccines should not be given to patients taking ADCO-PREDNISOLONE SYRUP because prednisolone (the active substance) can affect the way some vaccines work, making it (the vaccine) less effective (see section 2: “Do not take (or give) ADCO-PREDNISOLONE SYRUP).

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

- the following medicines, used together with ADCO-PREDNISOLONE SYRUP, may reduce the effects of ADCO-PREDNISOLONE SYRUP:
    - barbiturates (sedatives).
    - phenytoin, carbamazepine, primidone and phenobarbitone (medicines used to treat epilepsy / fits).
    - rifampicin and rifabutin (medicines used for treatment of tuberculosis).
    - aminoglutethimide, used to treat certain patients with Cushing's syndrome and some types of cancer.
    - immunosuppressants (medicines that reduce the activity of the body’s own immune system and used to treat certain auto-immune disorders, or after organ transplant to prevent organ rejection).
    - mifepristone (a medicine used to terminate pregnancy). Mifepristone will reduce the effects of ADCO-PREDNISOLONE SYRUP for 3 to 4 days after taking it.
- the following medicines, used together with ADCO-PREDNISOLONE SYRUP, may increase the effects of ADCO-PREDNISOLONE SYRUP, thereby increasing the chances of undesirable effects:
    - ritonavir and cobicistat (antiviral medicines used to treat HIV).

- erythromycin (an antibiotic, used to treat infections) and ketoconazole (used to treat fungal infections).
- ciclosporin (used to prevent rejection after organ transplant and in the treatment of rheumatoid arthritis).
- medicines containing estrogens (female sex hormone) including the contraceptive pill.

- hypokalaemia (low level of potassium in the blood) may result when ADCO-PREDNISOLONE SYRUP is used together with the following medicines:
  - diuretic medicines (water tablets) that deplete potassium, such as thiazides (e.g., hydrochlorothiazide) or furosemide.
  - medicines used in the treatment of asthma (or other conditions due to breathing difficulties) like theophylline, salbutamol, salmeterol, formoterol, fenoterol and terbutaline.
  - amphotericin, an antifungal medicine.
  - carbenoxolone, used in the treatment of stomach ulcers.
  - acetazolamide, used in the treatment of glaucoma and epilepsy.
- digoxin, used in the treatment of heart conditions. If low blood potassium levels occur, due to ADCO-PREDNISOLONE SYRUP, the chances of serious undesirable effects from digoxin is increased.
- anti-inflammatory medicines like salicylates, aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs), like diclofenac and ibuprofen, used for treating inflammation and pain. When taken together with ADCO-PREDNISOLONE SYRUP, your risk of severe stomach problems increases, along with an increased chance of undesirable effects.
- medicines used to treat high blood pressure (anti-hypertensives) and diabetes (antidiabetic medicine), including insulin. ADCO-PREDNISOLONE SYRUP may increase the requirements for such medicines and your doctor may need to adjust the dose of the

anti-hypertensive and / or anti-diabetic medicine (or medicines) you are taking.

- anti-coagulant medicines which prevent clotting (also known as blood thinners), for example warfarin. ADCO-PREDNISOLONE SYRUP may increase the response to anti-clotting medicines and you may be at an increased risk of bleeding. Your doctor is likely to monitor you more closely.
- somatropin (growth hormone), because the growth promoting effect may be stopped if used with ADCO-PREDNISOLONE SYRUP.
- medicines known as anti-muscarinics or anti-cholinesterases, used to treat conditions such as myasthenia gravis (a neuromuscular disorder that causes weakness in the muscles under your voluntary control). ADCO-PREDNISOLONE SYRUP may reduce the efficacy of these medicines (i.e., it does not work as well as it should).
- methotrexate, a medicine used for rheumatoid arthritis, psoriasis and certain types of cancer. If taken together with ADCO-PREDNISOLONE SYRUP, it may result in serious undesirable effects of the blood cells, possibly causing infection, bleeding or anaemia.
- medicines used to make X-rays clearer, as ADCO-PREDNISOLONE SYRUP may cause these medicines not to work as well as they should.

*Operations*

If you (or your child) are going to have an operation, tell the doctor that you are taking (or giving your child) ADCO-PREDNISOLONE SYRUP. Muscle relaxants are sometimes used during an operation or in an intensive care unit. These medicines and ADCO-PREDNISOLONE SYRUP can affect each other.

**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 taking this

medicine.

Do not take ADCO-PREDNISOLONE SYRUP if you are pregnant or breastfeeding.

ADCO-PREDNISOLONE SYRUP, may cause missed or irregular menstruation.

**Driving and using machines**

It is not always possible to predict to what extent ADCO-PREDNISOLONE SYRUP may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ADCO-PREDNISOLONE SYRUP affects you.

ADCO-PREDNISOLONE SYRUP should not affect your ability to drive or use machines. However, it may cause light-headedness (dizziness), headache and blurred vision. Therefore, you should not drive, use machinery or perform any tasks that require concentration until you are certain that ADCO-PREDNISOLONE SYRUP does not affect your ability to do so safely.

**ADCO-PREDNISOLONE SYRUP contains propylene glycol**

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them ADCO-PREDNISOLONE SYRUP, in particular if they use other medicines that contain propylene glycol or alcohol.

If you suffer from a liver or kidney disease, do not take ADCO-PREDNISOLONE SYRUP unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

**ADCO-PREDNISOLONE SYRUP contains glycerol**

ADCO-PREDNISOLONE SYRUP contains glycerol which may cause headache, stomach upset and diarrhoea.

**ADCO-PREDNISOLONE SYRUP contains alcohol**

ADCO-PREDNISOLONE SYRUP contains 4,8 % *v/v* alcohol (96,5 % *v/v*). This amount of alcohol is not likely to have an effect if you are an adult or adolescent, and its effects in children are not likely to be noticeable. However, it may have some effect if your child is younger, for example, it may make them feel sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking ADCO-PREDNISOLONE SYRUP.

**ADCO-PREDNISOLONE SYRUP contains sugar**

ADCO-PREDNISOLONE SYRUP contains invert syrup which may be harmful to the teeth.

ADCO-PREDNISOLONE SYRUP contains 625 mg of invert syrup, a mixture of fructose and glucose, per 5 ml syrup. This should be taken into account if you have diabetes.

ADCO-PREDNISOLONE SYRUP contains 625 mg sorbitol (a sugar alcohol) per 5 ml syrup, which is a source of fructose.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

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 (or are given) ADCO-PREDNISOLONE SYRUP.

**ADCO-PREDNISOLONE SYRUP contains benzoic acid**

ADCO-PREDNISOLONE SYRUP contains 5 mg benzoic acid per 5 ml syrup equivalent to 0,1 % *m/v*, included as a preservative.

Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

**ADCO-PREDNISOLONE SYRUP contains sodium**

ADCO-PREDNISOLONE SYRUP contains less than 1 mmol sodium (23 mg) per 5 ml syrup; that is to say it is essentially 'sodium-free'.

**3. How to take (or give) ADCO-PREDNISOLONE SYRUP**

Do not share medicines prescribed for you (or your child) with any other person.

Always take (or give) ADCO-PREDNISOLONE SYRUP exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

DO NOT TAKE MORE OF THIS MEDICINE THAN YOU SHOULD.

YOUR DOSING REQUIREMENTS MAY VARY DEPENDING ON THE SPECIFIC DISEASE, ITS SEVERITY AND YOUR RESPONSE TO THE MEDICATION. YOUR DOSAGE WILL THEREFORE BE DETERMINED BY YOUR DOCTOR TO SUIT YOUR REQUIREMENTS.

Shake the bottle before use

*Adults*

The usual adult dose is about 5 mg to 60 mg daily in divided doses. ADCO-PREDNISOLONE SYRUP may be given daily as a single dose after breakfast or as a double dose on alternate (every other) days not exceeding the maximum dose.

*Infants and children*

The usual daily dose in infants and children of ADCO-PREDNISOLONE SYRUP is 0,5 mg to 2 mg per kg of body weight or 15 to 60 mg per square meter of body surface area in three

divided doses.

The dose varies according to the disease being treated.

Your doctor may need to change the starting dose to obtain a satisfactory response.
Your doctor will reduce the daily dose of the medicine once your condition has stabilised.

Your doctor will tell you how long your treatment with ADCO-PREDNISOLONE SYRUP will last. Do not stop treatment early because this may result in undesirable side effects. If you have the impression that the effect of ADCO-PREDNISOLONE SYRUP is too strong or too weak, tell your doctor or pharmacist.

**If you take (or give) more ADCO-PREDNISOLONE SYRUP 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 (or give) ADCO-PREDNISOLONE SYRUP**

Do not take (or give) a double dose to make up for forgotten individual doses.

**If you stop taking (or giving) ADCO-PREDNISOLONE SYRUP**

Your doctor will tell you how long your (or your child's) treatment with ADCO-PREDNISOLONE SYRUP will last. Do not stop taking (or giving) this medicine without talking to your doctor first, because the dose might need to be reduced slowly over a period of time (weeks or months, depending on how long you, or your child, received treatment with ADCO-PREDNISOLONE SYRUP).
Stopping ADCO-PREDNISOLONE SYRUP treatment (especially if stopped suddenly), can lead

to serious problems of the adrenal gland, known as “withdrawal” symptoms. The most common are:

- high temperature (fever);
- muscle and joint pain;
- runny nose;
- red, sore and sticky eyes (conjunctivitis);
- painful itchy skin lumps;
- weight loss;
- being sick (vomiting);
- low blood pressure causing you to feel faint;
- headache;
- blurred vision;
- reappearance of your disease symptoms.

If you or your child experience withdrawal symptoms or think you (or your child) might have withdrawal symptoms, tell your doctor straight away. He/she may ask you to start taking ADCO-PREDNISOLONE SYRUP (or giving it to your child) again and then to start coming off it again more slowly.

You (or your child) are more likely to experience withdrawal symptoms if:

- you (or your child) have been taking ADCO-PREDNISOLONE SYRUP for more than 3 weeks.
- you (or your child) have been treated with a steroid, like ADCO-PREDNISOLONE SYRUP, repeatedly.
- you (or your child) have previously taken a steroid, like ADCO-PREDNISOLONE SYRUP, for a long period of time (months or years), and now you have received an acute (short term) course of ADCO-PREDNISOLONE SYRUP.
- the daily dose is more than 40 mg daily (approximately 13,3 ml per day).

- you (or your child) repeatedly take doses of ADCO-PREDNISOLONE SYRUP at night.

**4. Possible side effects**

ADCO-PREDNISOLONE SYRUP can have side effects.

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

If any of the following happens, stop taking ADCO-PREDNISOLONE SYRUP (or giving it to your child) 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 (or your child) may have had a serious reaction to ADCO-PREDNISOLONE SYRUP. 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:

- a very sore throat, sudden onset of fever, low body temperature, shaking, chills, confusion or difficulty breathing. These may be signs that your body is fighting an infection, which may be serious and severe. You may also have difficulty in swallowing and the inside of your mouth may have white areas on the surface. Remember that your sensitivity to all

kinds of infection may be increased and ADCO-PREDNISOLONE SYRUP may mask the signs and symptoms of infection.

- coughing for a few weeks, coughing up blood or mucous, tiredness and night sweats (which may be due to tuberculosis, also known as TB).
- painless coloured (red, purple, brown or black) spots on the legs, feet or face which can also appear in the genital area or mouth. These skin lesions may be a sign of a rare type of cancer which can affect both the skin and internal organs known as Kaposi's sarcoma.
- fits (also known as convulsions and seizures). If you have epilepsy you may notice you get fits (seizures) more often than usual or they are more severe.
- slow heart rate, chest pain, shortness of breath, fainting, swelling in the legs or feet. These may be signs and symptoms of heart problems like bradycardia (slow heart rate) and heart failure (where the heart is not pumping correctly).
- rapid or irregular heartbeat, feeling lightheaded (dizzy), excessive sweating, clammy or bluish discoloured skin or leg pain or swelling (or both), usually in the calf. These might be signs of a clot in your lungs or legs.
- severe headaches, nausea and vomiting and loss of vision. These may be signs of increased pressure in the brain known as benign intra-cranial hypertension, especially in children.
- severe upper stomach pain with nausea or vomiting. These may be signs of a problem with your pancreas (inflammation of the pancreas).
- severe stomach pain (in your mid-to upper abdomen), vomiting blood or blood in stool (which can look like dark or black stool). These may be due to ulcers in the stomach, intestines or food pipe (gullet). You may also experience nausea and vomiting, heartburn, chest pain, pain when swallowing or feeling bloated.
- ongoing pain in any joint, as this might be a sign of osteonecrosis (death of bone tissue). Initially, you may not have any symptoms due to osteonecrosis; however, as the condition

worsens, affected joints might hurt only when putting weight on them. Eventually, you might feel the pain even when you're lying down. The pain can be mild or severe.

- sudden high blood pressure, kidney failure and passing less urine, due to scleroderma renal crisis. This can especially happen if you have sclerosis. You may experience symptoms due to an increase in blood pressure including headache, dizziness, nausea (feeling sick), shortness of breath, seizures or problems with your eyesight.
- signs of “withdrawal” after you have stopped taking ADCO-PREDNISOLONE SYRUP (see section 3: “If you stop taking (or giving) ADCO-PREDNISOLONE SYRUP”).

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

Tell a doctor straight away if you notice any of the following side effects:

*Serious mental health problems*

- feeling severely depressed, including thinking about suicide.
- feeling high (mania) or an exaggerated state of happiness (euphoria).
- moods that go up and down.
- feeling irritable or anxious.
- difficulty in thinking or being confused.
- loss of memory.
- having problems sleeping (insomnia).
- feeling, seeing and hearing things that are not real (or if you suffer from schizophrenia the condition may worsen).
- changes in how you feel or act.

Steroids like, and including, ADCO-PREDNISOLONE SYRUP can less frequently cause serious mental health problems. If you notice any of these problems talk to a doctor as soon as possible.

*Wound heading*

- delayed (slow) or improper wound healing (wounds and cuts do not heal as quickly as

usual or not as well as it should).

*Eye problems*

- changes in your vision (how you see) like sudden appearance of many floaters or blurred vision or bulging (protruding) of the eyes. These may be signs of eye problems such as glaucoma (increased eye pressure), cataracts (clouding of the lens of the eyes) or other serious eye problems.

The following side effects have been reported:

*Frequent:*

- increased appetite.
- osteoporosis.
- spontaneous fractures (breaks in your bones).

*Less frequent:*

- increase in blood sugar levels which may cause (or worsen) diabetes. Your diabetic medication may need to be increased.
- increased sweating.

*The following side effects have been reported and the frequencies are unknown:*

- Moon-face (filling or rounding out of the face), sometimes hirsutism (excessive growth of hair of normal or abnormal distribution), buffalo hump (increased amount of fat in the upper back and neck), flushing, increased bruising, acne and striae (reddish purple lines on arms, face, groin, legs or trunk).
- sodium and water retention with swelling, high blood pressure and disturbances in electrolyte (salt) balance.
- low levels of potassium in the blood, which may result in tiredness, confusion or muscle

cramps.

- muscle weakness or pain.
- menstrual (period) irregularities such as excessive, delayed or absence of period (amenorrhoea).
- disturbances of the nervous system, dizziness (feeling lightheaded) and headache.
- blurred vision.
- worsening of eye infections (viral or fungal).
- vertigo causing a spinning sensation or a feeling of being unbalanced with or without nausea and ringing in ears (or hearing loss).
- hiccups, indigestion, feeling bloated, feeling sick (nausea), being sick (vomiting), stomach pain, diarrhoea.
- thin delicate skin, unusual marks on the skin or bruising, appearance of stretch marks, acne, rash, itching and hives.
- tendon rupture (when a muscle is torn from the bone at the point of attachment).
- general feeling of being unwell.
- growth retardation in children.
- increase in weight.

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 "**6.04 Adverse Drug Reaction 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 ADCO-PREDNISOLONE SYRUP.

## 5. How to store ADCO-PREDNISOLONE SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light.

Store in the original container protected from light.

Keep the container tightly closed and do not store the product in bathrooms in order to protect from moisture.

Do not use after the expiry date on the label.

Return all unused medicine to your pharmacist. Do not dispose unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What ADCO-PREDNISOLONE SYRUP contains

- The active substance is prednisolone.

  The active substance per one medicine measure (5 ml) is 15 mg Prednisolone.
- The other ingredients are: Propylene glycol, glycerol, 4,8 % *v/v* alcohol (96,5 %), saccharin sodium, invert sugar, sorbitol 70 % solution, acid citric monohydrate, disodium edetate, 0,1 % *m/v* acid benzoic (preservative), polyvinylpyrrolidone K25, purified water, blackcurrant flavour 75171-33, masking flavour 11031-33 and colour red ger C.I.No. 16255 and C.I.No. 45430

### What ADCO-PREDNISOLONE SYRUP looks like and contents of the pack

ADCO-PREDNISOLONE SYRUP is a clear, cherry-red syrup with a blackcurrant odour and taste and a slight bitter after taste.

ADCO-PREDNISOLONE SYRUP is packed in amber glass bottles of 50 ml, 100 ml, 200 ml and

500 ml.

White Polypropylene 28 mm Cap with Liner

Not all pack sizes may be marketed.

**Holder of Certificate of Registration**

Adcock Ingram Limited

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