PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SOLU-CORTEF® 100 mg Injection (Vial)

SOLU-CORTEF® 100 mg Injection (Act-O-Vial)

Hydrocortisone sodium succinate

Sugar free

Read all of this leaflet carefully before you are given SOLU-CORTEF

- 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.
- SOLU-CORTEF 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 SOLU-CORTEF is and what it is used for
2. What you need to know before you are given SOLU-CORTEF
3. How to receive SOLU-CORTEF
4. Possible side effects
5. How to store SOLU-CORTEF
6. Contents of the pack and other information

1. What SOLU-CORTEF is and what it is used for

SOLU-CORTEF is a type of cortisone. It will be injected by a doctor if your body cannot produce enough corticosteroid due to problems with your adrenal glands (e.g. adrenal insufficiency). Corticosteroids can also help treat shock following surgery, injuries, hypersensitivity (anaphylactic) reactions or other stressful conditions, swelling and pain caused by autoimmune diseases, or to control very strong allergic reactions or severe infections. These include inflammatory or allergic conditions e.g. lupus (systemic lupus erythematosus), severe asthma or breathing vomit into your lungs while unconscious.

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Ask your doctor if you are unsure why you have been given this medicine.

2. What you need to know before you are given SOLU-CORTEF

Apart from in an emergency, SOLU-CORTEF should not be administered to you:

- if you are hypersensitive (allergic) to hydrocortisone sodium succinate or any of the other ingredients of SOLU-CORTEF (listed in section 6); an allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath
- if you have a systemic fungal infection
- if you have brain injury due to trauma
- if you have a herpes eye infection
- if you suffer from severe depression, manic depression (bipolar disorder) or psychotic tendencies
- if you have suffered tuberculosis (TB) in the past
- if you have recently had, or are about to have certain types of vaccines

Speak to your doctor or health care provider immediately if any of the above applies to you.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

Take special care with SOLU-CORTEF:

- if you have unusual stress
- if your treatment with SOLU-CORTEF is stopped quickly. Stopping treatment too quickly may cause withdrawal symptoms including loss of appetite, nausea, vomiting, tiredness, headache, fever, joint pain, skin peeling, muscle aches, weight loss and low blood pressure.
- if you have Cushing’s disease (condition caused by an excess of cortisol hormone in your body)
- if you are suffering from an infection of any type (including fungal infections)
- if you have chickenpox, measles or shingles If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them
- if you have tuberculosis (TB) or if you have suffered TB in the past

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- if you have recently had or are about to have a vaccine
- if you have or develop Kaposi's sarcoma (a type of skin cancer)
- if you have septic shock (a dangerous drop in blood pressure caused by severe infection)
- if you have experienced an allergy to any medicine or if you develop symptoms of an allergic reaction to SOLU-CORTEF including skin rash, swelling of the face, wheezing or difficulty breathing, light headedness, fast heartbeat, sweating or loss of consciousness
- if you have liver disease
- if you develop eye problems including blurred vision or other visual disturbances, bulging or protruding of the eyeballs or increased pressure in the eye causing eye pain and headaches
- if you have risk factors for heart problems including hypertension (high blood pressure), abnormal levels of fats in the blood (e.g., cholesterol) or symptoms of heart failure (e.g., swollen ankles, difficulty breathing, rapid or irregular heartbeat)
- if you have a history of thrombosis (formation of blood clots inside a blood vessel)
- if you have hypertension (high blood pressure)
- if you have severe depression or manic depression (bipolar disorder), psychotic tendencies or thoughts of suicide; this includes having had depression before while taking steroid medicines like SOLU-CORTEF, or having a family history of these illnesses
- if you have a history of convulsions (fits/seizures)
- if you have myasthenia gravis (a condition causing tired and weak muscles)
- if you have symptoms of epidural lipomatosis, a disorder in which an abnormal amount of fat is deposited on or outside the lining of the spine (e.g., back pain or weakness, pins and needles or paralysis)
- if you develop symptoms of pancreatitis (inflammation of the pancreas which causes severe pain in the stomach and back)
- if you have a history of stomach ulcers or other serious stomach or intestinal problems (e.g., ulcerative colitis)
- if you have had muscle problems (pain or weakness) while taking steroid medicines in the past
- if you have osteoporosis (brittle bones)
- if you have kidney problems

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- if you are taking cobicistat, a medicine used to treat HIV infections
- if you are taking aspirin or other non-steroidal anti-inflammatory drugs (also called NSAIDs)
- if you have phaeochromocytoma (a tumour of your adrenal gland)
- if you have a head or brain injury or stroke
- if you have diabetes

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

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 doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Mental problems while receiving SOLU-CORTEF

Mental health problems can happen while receiving steroids like SOLU-CORTEF (see section 4).

- These illnesses can be serious.
- Usually they start within a few days or weeks of starting SOLU-CORTEF.
- Most of these problems go away if the dose is lowered or SOLU-CORTEF is stopped. However if the problems do happen they might need treatment.

Tell a doctor or health care provider if you show any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide. In a few cases mental problems have happened when doses are being lowered or stopped.

Children and adolescents

Corticosteroids can suppress growth in children so your doctor will prescribe the lowest dose that will be effective for your child.

SOLU-CORTEF may increase risk of hypertrophic cardiomyopathy (thickening of heart muscle) in

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prematurely born infants, therefore your health care provider may test and monitor for this condition.

Other medicines and SOLU-CORTEF

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

This includes taking medicines available without a prescription (e.g. cough and cold medicines). The use of SOLU-CORTEF with these medicines may cause undesirable interactions. Please consult your doctor or health care provider for advice.

You should tell your doctor or health care provider if you are taking any of the following medicines which can affect the way SOLU-CORTEF or the other medicine works:

- Antibiotics (such as isoniazid, erythromycin, clarithromycin and troleandomycin)
- Antibiotics used to treat tuberculosis (TB) such as rifampicin
- Medicines used to 'thin' the blood (anticoagulants) such as warfarin
- Medicines used to treat epilepsy such as carbamazepine, phenytoin and phenobarbital (phenobarbitone)
- Neuromuscular blocking medicines which are used in some surgical procedures such as pancuronium and vecuronium
- Medicines used to help block involuntary muscle movement associated with disease called anticholinergics
- Medicines used to treat myasthenia gravis (a muscle condition) called anticholinesterases
- Medicines used to treat high blood sugar (antidiabetics)
- Medicines used to stop you from being sick called antiemetics (such as aprepitant and fosaprepitant)
- Medicines used to treat fungal infections such as ketoconazole or itraconazole
- Medicines used to treat HIV infections called HIV-protease inhibitors (such as indinavir and ritonavir) and pharmacokinetic enhancers (such as cobicistat)
- Medicines used for treating cancer such as aminoglutethimide
- Medicines used for heart problems or high blood pressure such as diltiazem
- Medicines used for heart failure and/or an irregular heartbeat such as digoxin

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- Oral contraceptives such as ethinylestradiol and norethindrone
- Medicines containing estrogens
- Medicines used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant such as ciclosporin
- Medicines used following an organ transplant to prevent rejection of the organ such as tacrolimus
- Medicines used to treat mild to moderate pain such as aspirin and other non-steroidal anti-inflammatory drugs (also called NSAIDs)
- Medicines used to increase the excretion of urine called diuretics (sometimes called water tablets)
- Medicines used to treat asthma such as xanthines or beta2 agonists

If you are taking long term medicine(s)

If you are being treated with medicines to thin the blood, tell your doctor as he/she may need to adjust the dose of the medicines used to treat this condition.

Before you have any operation, tell your doctor or health care provider that you are receiving SOLU-CORTEF.

If you require a test to be carried out by your doctor or in hospital it is important that you tell the doctor or health care provider that you are receiving SOLU-CORTEF as this medicine can affect the results of some tests.

SOLU-CORTEF with food and drink

Do not drink grapefruit juice while receiving SOLU-CORTEF.

Pregnancy and breastfeeding

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

Safety in pregnancy and lactation has not been proven.

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Small amounts of corticosteroid medicines may get into your breast milk. This may suppress growth in the nursing infant.

Driving and using machines

SOLU-CORTEF may make you feel tired, faint, dizzy or may affect your vision after treatment.

If you are affected do not drive or operate any tools or machinery.

It is not always possible to predict to what extent SOLU-CORTEF may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SOLU-CORTEF affects them.

3. How to receive SOLU-CORTEF

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

While you are receiving SOLU-CORTEF, you should tell any health care provider who gives you treatment that you are receiving SOLU-CORTEF.

You will not be expected to give yourself SOLU-CORTEF. It will be given to you by a person who is qualified to do so.

Dosage information

Your doctor will decide on whether to inject into a vein (intravenous) or into a muscle (intramuscular), how much SOLU-CORTEF and how many injections you will receive depending on the condition being treated and its severity. Your doctor will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

SOLU-CORTEF is not recommended for intrathecal or epidural use.

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Adults

Your doctor or health care provider will tell you how many injections you will require for the condition you are being treated for, and when you will get them.

Elderly

Treatment will normally be the same as for younger adults.

If you have the impression that the effect of SOLU-CORTEF is too strong or too weak, tell your doctor or pharmacist.

If you receive more SOLU-CORTEF than you should

Since a health care provider will administer SOLU-CORTEF, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

If you forget to receive SOLU-CORTEF

Since a health care provider will administer SOLU-CORTEF, it is unlikely that the dose will be missed.

If you miss a dose of SOLU-CORTEF speak to your doctor or health care provider as soon as possible.

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

If you stop receiving SOLU-CORTEF

Your doctor will decide when it is time to stop your treatment.

You will need to come off SOLU-CORTEF slowly to avoid withdrawal symptoms. These symptoms may include loss of appetite, nausea, vomiting, tiredness, headache, fever, skin peeling, muscle and joint pains, weight loss and low blood pressure.

If your symptoms seem to return or get worse as your dose of SOLU-CORTEF is reduced, tell your doctor or health care provider immediately.

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4. Possible side effects

SOLU-CORTEF can have side effects.

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

In certain medical conditions, medicines like SOLU-CORTEF (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek medical attention immediately. Your doctor will then decide whether you should continue receiving SOLU-CORTEF.

Tell your doctor immediately if any of the following happens:

- *Allergic reactions*, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.
- *Pancreatitis*, stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- *Burst or bleeding ulcers*, symptoms of which are severe stomach pain which may go through to the back and could be associated with bleeding from your rectum, black or blood-stained stools and/or vomiting blood.
- *Infections,* SOLU-CORTEF can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage. Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a previous TB infection could be coughing blood or pain in the chest. SOLU-CORTEF may also make you more likely to develop a severe infection.
- *Raised pressure within the skull*, the symptoms of which are headaches with vomiting, lack of energy and drowsiness.

These are all very serious side effects. If you have them, you may have had a serious reaction to SOLU-CORTEF. You may need urgent medical attention or hospitalisation.

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Tell your doctor if you notice any of the following:

Frequent side effects

- infections
- round or moon-shaped face (Cushingoid)
- hypothalamic pituitary adrenal axis suppression; steroid withdrawal syndrome - a short supply of one or more pituitary hormones. This can affect a number of things including growth (in children, poor overall growth and short height; in adults, reduced energy), blood pressure (may be lowered) and reproduction (in women, periods may stop; in men, decreased sperm production and loss of sexual function; in children, delayed puberty may occur)
- sodium retention, which causes thirst due to dehydration
- diabetes or need for existing diabetics to use more insulin
- high blood pressure, symptoms of which are headaches, or generally feeling unwell
- small purple/red patches/blisters on or under the skin
- brittle bones (bones that break easily)
- slowing of normal growth
- decreased carbohydrate tolerance
- decreased blood potassium

Less frequent side effects

- allergic reactions, such as skin rash, swelling of the face, wheezing and difficulty breathing
- sudden, severe allergic reaction with difficulty breathing, swelling, light headedness, fast heartbeat, sweating or loss of consciousness
- fluid retention, which causes swelling that may be widespread, or confined to a limb or part of a limb
- low levels of potassium in the body; this may cause irritability, muscle twitching and cramps, and tingling in your fingers, toes and around the lips
- metabolic acidosis (build-up of too much acid in the body; this may cause nausea, vomiting, fast breathing and tiredness)
- SOLU-CORTEF can cause serious mental health problems:

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  - feeling depressed
  - feeling high (euphoria)
  - changes in expressing emotions
  - medicine dependence
  - thinking about suicide
  - changes to personality and behaviour (the way you act)
  - moods that go up and down (mood swings)
  - having problems sleeping
- raised pressure within the skull (symptoms are headaches with vomiting, lack of energy and drowsiness)
- cataracts (clouding of the lens)
- protruding of the eyeballs (exophthalmos)
- ulcers in the stomach or the duodenum (abdominal pain, nausea, vomiting)
- pancreatitis (inflammation of the pancreas, causing stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- thinning of your skin
- hives
- breakdown of bone due to poor circulation of blood, this causes pain in the hip
- muscle disease causing weakness (myopathy)
- bone fractures
- poor wound healing
- increase in the pressure in your eye
- increased calcium in your urine
- tearing (rupturing) of tendons particularly the Achilles tendon

Other side effects

- increased likelihood of infections
- a type of cancer that causes tumours to grow under the skin which is known as Kaposi’s sarcoma
- increased number of white blood cells (leucocytosis)

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- increased insulin requirement
- back pain or weakness (due to epidural lipomatosis, a disorder in which an abnormal amount of fat is deposited on or outside the lining of the spine). Pins and needles and paralysis may also be experienced.
- increase in the pressure in your head (brain)
- convulsions (fits/seizures)
- blurred or distorted vision (due to a disease called central serious chorioretinopathy) with detachment of the retina
- problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heartbeat) or irregular beating of the heart, irregular or very fast or slow pulse
- formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system
- clot in a blood vessel in the lungs (pulmonary embolism)
- gasping syndrome
- gastric haemorrhage (you may experience vomiting blood, which might be red or might be dark brown and resemble coffee grounds in texture, black or tarry stool, rectal bleeding, usually in or with stool and light headedness)
- inflammation of the oesophagus (oesophagitis) – the tube that leads from your throat to stomach, including ulcers of the oesophagus (you may experience difficulty, painful swallowing/heartburn, chest pain)
- intestinal perforation – a hole develops in the wall of the intestines
- bruising
- muscle weakness
- irregular or absent periods (menstruation)
- abnormal liver function tests
- suppression of reactions to skin tests
- fractures in the spine
- medicine withdrawal syndrome with symptoms including loss of appetite, nausea, vomiting,

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tiredness, headache, fever, joint pain, skin peeling, muscle aches, weight loss and low blood pressure

- abnormal level of fats in the blood (e.g. cholesterol)
- abnormal fat deposition in the body
- increased appetite
- increased weight
- psychotic disorders including feeling, seeing or hearing things that are not there
- changes in mental status
- confusion
- anxiety
- abnormal behaviour
- irritability
- memory loss
- difficulty thinking
- dizziness
- headache
- glaucoma (increased pressure in the eye causing eye pain and headaches)
- vertigo (sensation of rotation or movement of oneself or the surrounding)
- hypertrophic cardiomyopathy (thickening of heart muscle) in prematurely born infants
- low blood pressure
- hiccups
- bloated stomach
- abdominal pain
- diarrhoea
- indigestion
- nausea
- rapid swelling under the skin in areas such as the face, throat, arms and legs (angioedema)
- excessive growth of body and facial hair (hirsutism)
- reddening of the skin

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- increased sweating
- stretch marks (skin striae)
- rash
- itching
- acne
- pale (light-coloured) patches of skin
- muscle pain
- muscle weakness or wasting
- bone and joint changes related to loss of sensation
- joint pain
- swelling of the extremities (e.g., ankles)
- tiredness
- feeling generally unwell (malaise)
- skin reactions at the site of injection
- increased blood urea

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 or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SOLU-CORTEF.

5. How to store SOLU-CORTEF

- Store all medicines out of reach of children.
- SOLU-CORTEF 100 mg Vial and 100 mg Act-O-Vial:

  Store the unmixed medicine at or below 25 °C.

  Once the medicine has been mixed as directed the solution should be used straight away. Any

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unused liquid should be disposed of safely.

- Do not use SOLU-CORTEF after the expiry date stated on the label and carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SOLU-CORTEF contains

- The active substance is hydrocortisone sodium succinate.

  SOLU-CORTEF 100 mg Vial: Each vial contains hydrocortisone sodium succinate equivalent to 100 mg hydrocortisone.

  SOLU-CORTEF 100 mg Act-O-Vial: A two-compartment vial containing per 2 mL (when mixed), hydrocortisone sodium succinate equivalent to 100 mg hydrocortisone.

- The other ingredients are monobasic sodium phosphate monohydrate, dibasic sodium phosphate dried and water for injection (Act-O-Vial).

What SOLU-CORTEF looks like and contents of the pack

SOLU-CORTEF 100 mg Vial: White to off-white powder or caked powder.

SOLU-CORTEF 100 mg Act-O-Vial: A two-compartment glass vial. The upper compartment contains a clear, colourless solution and the lower compartment contains a white to off-white powder or caked powder.

SOLU-CORTEF 100 mg Vial: 100 mg vial

SOLU-CORTEF 100 mg Act-O-Vial: 2 mL Act-O-Vial

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Limited

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