

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S4**

**SOLU-CORTEF® 100 mg Injection**  
**SOLU-CORTEF® 100 mg Injection (Act-O-Vial)**  
**SOLU-CORTEF® 500 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.

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 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 a history of ulcers or suffer from other intestinal illness
- if you have Cushing's disease (condition caused by an excess of cortisol hormone in your body)
- if you have diabetes
- if you have kidney problems
- if you have a history of blood clots
- if you have high blood pressure
- if you have a skin condition or suffering a fungal infection
- if you have recently had, or are about to have any vaccination

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 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 tuberculosis in the past
- if you have hypertension (high blood pressure)
- if you have experienced an allergy to any medicine
- if you have kidney or liver disease
- if you have severe depression or manic depression (bipolar disorder) or psychotic tendencies; this includes having had depression before while taking steroid medicines like SOLU-CORTEF, or having a family history of these illnesses
- if you have stomach ulcer or other serious stomach or intestinal problems (ulcerative colitis)
- if you have osteoporosis (brittle bones)
- if you have myasthenia gravis (a condition causing tired and weak muscles)
- if you have thrombosis (formation of blood clots inside a blood vessel)
- if you have had muscle problems (pain or weakness) while taking steroid medicines in the past
- if you have Kaposi's sarcoma (a type of skin cancer)
- if you have pheochromocytoma (a tumour of your adrenal gland)
- if you have head injury or stroke

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

#### *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.

### **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)
- Medicines used for treating cancer such as aminoglutethimide
- Medicines used for heart problems or high blood pressure such as diltiazem
- Oral contraceptives such as ethinylestradiol and norethindrone

- 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 xanthenes 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.

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.

### **SOLU-CORTEF Act-O-Vial contains benzyl alcohol**

SOLU-CORTEF Act-O-Vial contains benzyl alcohol and must not be given to premature babies or newborn babies. It may cause toxic and allergic reactions in infants and children.

### **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.

#### *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.

### *Children*

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

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 overdose your doctor will manage the overdose.

### **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 itchy skin, fever, muscle and joint pains.

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.

#### 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.

Tell your doctor if you notice any of the following:

*Frequent side effects*

- infections
- round or moon-shaped face (Cushingoid)
- hypopituitarism - 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 existing 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*

- 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 blood
- alkalosis (the blood becoming too alkaline). This may cause irritability, muscle twitching and cramps, and tingling in your fingers, toes and around the lips
- SOLU-CORTEF can cause serious mental health problems:
  - feeling depressed
  - feeling high or moods that go up and down (mood swings)
  - psychotic disorder including feeling, seeing or hearing things which are not there
  - having problems sleeping
  - changes to personality and behaviour (the way you act)
  - worsening of existing psychiatric conditions
- cataracts (clouding of the lens)

- protruding of the eyeballs (exophthalmos)
- ulcers in the stomach or the duodenum (abdominal pain, nausea, vomiting)
- thinning of your skin
- bone fractures
- breakdown of bone due to poor circulation of blood, this causes pain in the hip
- poor wound healing
- increase in the pressure in your eye
- increased calcium in your urine
- negative nitrogen balance
- 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)
- may suppress reactions to skin test
- other nervous system side effects may include convulsions (fits/seizures)
- increase in the pressure in your head (brain)
- 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.
- blurred or distorted vision (due to a disease called central serous 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
- 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
- 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)
- bruising
- muscle weakness
- irregular or absent periods (menstruation)
- abnormal liver function tests
- increased insulin requirement
- fractures in the spine

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
- Store both the unmixed medicine as well as the solution between 15 °C - 30 °C
- Protect from light
- Unused solutions should be thrown away 3 days after being mixed
- 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 Injection: 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.

SOLU-CORTEF 500 mg Act-O-Vial: A two-compartment vial containing per 4 mL (when mixed), hydrocortisone sodium succinate equivalent to 500 mg hydrocortisone.

- The other ingredients are monobasic sodium phosphate monohydrate, dibasic sodium phosphate dried, benzyl alcohol (preservative) 0,9 % m/v (Act-O-Vial) and water for injection (Act-O-Vial).

### **What SOLU-CORTEF looks like and contents of the pack**

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

SOLU-CORTEF 100 mg and 500 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 Injection: 100 mg vial

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

SOLU-CORTEF 500 mg Act-O-Vial: 4 mL Act-O-Vial

### **Holder of Certificate of Registration**

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