SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE

SOLU-CORTEF® 100 mg Injection

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

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for injection.

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.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sterile SOLU-CORTEF is indicated in corticosteroid responsive conditions when the oral route of corticosteroid administration is not suitable.

Acute adrenocortical insufficiency

Prior to and immediately after bilateral adrenalectomy

Severe shock

In severe shock adjunctive use of intravenous SOLU-CORTEF may aid in achieving haemodynamic restoration. Corticoid therapy should not replace standard methods of combating shock. For information on the use of SOLU-CORTEF in septic shock, refer to section 4.4.

Acute hypersensitivity reactions

In *status asthmaticus*, and allergic medicine anaphylactic reactions, epinephrine (adrenaline) should be given before or along with SOLU-CORTEF.

4.2 Posology and method of administration

SOLU-CORTEF may be administered by intravenous injection, by intravenous infusion, or by intramuscular injection. The preferred method for initial emergency use is intravenous injection. Following the initial period, consideration should be given to employing a longer acting injectable preparation or an oral preparation.

Posology

Therapy is initiated by administering SOLU-CORTEF intravenously over a period of one to several minutes. In general, high dose corticosteroid therapy should be continued only until the patient's condition has

stabilised – usually not beyond 48 to 72 hours. Although adverse effects associated with high dose, short-term corticoid therapy are uncommon, peptic ulceration may occur. Prophylactic antacid therapy may be indicated.

When massive hydrocortisone therapy must be continued beyond 48 – 72 hours, hypernatraemia may occur. Under such circumstances it may be desirable to replace SOLU-CORTEF with a corticoid such as methylprednisolone sodium succinate which causes little or no sodium retention.

In other situations in which adequate preparations with intramuscularly administered cortisone or hydrocortisone cannot be accomplished, the initial dose is 100 to 500 mg, depending on the severity of the condition, administered by intravenous injection over a period of at least 30 seconds.

This dose may be repeated at intervals of 1, 3, 6 and 10 hours, as indicated by the patient's response and clinical condition.

Patients subjected to severe stress following corticosteroid therapy should be observed closely for signs and symptoms of adrenocortical insufficiency.

SOLU-CORTEF therapy is an adjunct to, and not a replacement for, conventional therapy.

Special populations

Hepatic impairment

In patients with liver disease, there may be an increased effect (see section 4.4) and reduced dosing may be considered.

Paediatric population

While the dose may be reduced for infants and children, it is governed more by the severity of the condition and response of the patient, than by age or body mass, but should not be less than 25 mg daily.

Method of administration

For intravenous injection, intravenous infusion or intramuscular injection.

For instructions on reconstitution and dilution of the product before administration, see section 6.6.

4.3 Contraindications

SOLU-CORTEF is contraindicated:

- in patients who have systemic fungal infections
- in patients with known hypersensitivity to hydrocortisone sodium succinate or any of the excipients of SOLU-CORTEF listed in section 6.1.
- Traumatic brain injury

Except when used for short-term or emergency therapy as in acute sensitivity reactions, SOLU-CORTEF is absolutely contraindicated in patients with herpes simplex keratitis, acute psychoses, and in patients with latent, healed or arrested tuberculosis. However, concurrent administration of corticoids with antituberculous medicines may be lifesaving in certain cases of meningeal tuberculosis. The following conditions are considered to be relative contraindications: active or latent peptic ulcer, Cushing's syndrome, diverticulitis, recent intestinal anastomoses, osteoporosis, renal insufficiency, thromboembolic tendencies, psychotic tendencies, diabetes mellitus, hypertension, local or systemic infections including vaccinia and varicella, as well as fungal diseases and other exanthematous diseases.

Pregnancy is a relative contraindication to corticoid therapy particularly during the first trimester because of the observation of foetal abnormalities in experimental animals. If it is necessary to give corticosteroids during pregnancy, the newborn infant should be observed closely for signs of hypoadrenalism and appropriate therapy instituted if such signs are present.

If corticoids are employed in the above conditions the risks should be weighed against possible benefits.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving

immunosuppressive doses of corticosteroids.

4.4 Special warnings and precautions for use

SOLU-CORTEF should be given only with full knowledge of the characteristic activity of, and the varied responses to adrenocortical hormones.

In patients on corticosteroid therapy subjected to unusual stress, increased dosage or rapidly acting corticosteroids before, during and after the stressful situation is indicated.

Corticosteroids such as SOLU-CORTEF may mask signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localise infection when corticosteroids are used. Infections with any pathogen including viral, bacterial, fungal, protozoan or helminthic infections, in any location in the body, may be associated with the use of corticosteroids alone or in combination with other immunosuppressive medicines that affect cellular immunity, humoral immunity, or neutrophil function. These infections can be severe and may be fatal. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases.

The use of SOLU-CORTEF in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with appropriate antituberculosis regimen.

Administration of live or live, attenuated vaccines is contraindicated in patients receiving SOLU-CORTEF. Killed or inactivated vaccines may be administered to patients receiving immunosuppressive doses of corticosteroids; however, the response to such vaccines may be diminished.

SOLU-CORTEF can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. Dietary salt restriction and potassium supplementation may be necessary. Corticosteroids increase calcium excretion.

Hypersensitivity reactions may occur, including anaphylactoid reactions (e.g. bronchospasm). Appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any medicine.

SOLU-CORTEF may have increased adverse effects in patients with liver disease since the metabolism and elimination of hydrocortisone is significantly decreased in these patients.

Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation.

Corticosteroid therapy has been associated with central serous chorioretinopathy, which may lead to retinal detachment.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

There have been reports of epidural lipomatosis in patients taking corticosteroids, typically with long-term use at high doses. The onset of symptoms is usually gradual. The symptoms may include back pain and sensory or motor disorders.

Corticosteroids should be used with caution in ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infections, also in diverticulitis, intestinal anastomoses, active or latent peptic ulcer, renal insufficiency, hypertension, osteoporosis, and myasthenia gravis.

Thrombosis including venous thromboembolism has been reported to occur with corticosteroids. As a result corticosteroids should be used with caution in patients who have or may be predisposed to thromboembolic disorders.

An acute myopathy has been described with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission (e.g. myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking medicines (e.g. pancuronium). This acute myopathy is generalised, may involve ocular and respiratory muscles, and may result in quadriparesis. Elevations of creatine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years.

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy. Discontinuation of corticosteroids may result in clinical remission.

The role of corticosteroids in septic shock has been reported to have both beneficial and detrimental effects. Their routine use in septic shock is not recommended, and a systematic review concluded that short-course, high-dose corticosteroids were not supported by the data. However, meta-analyses and a review suggest that longer courses (5 -11 days) of low dose corticosteroids might reduce mortality, especially in patients with vasopressor dependent septic shock.

Phaeochromocytoma crisis, which can be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids should only be administered to patients with suspected or identified phaeochromocytoma after an appropriate risk/benefit evaluation.

Systemic corticosteroids are not indicated for, and therefore should not be used to treat traumatic brain injury; a multicentre study revealed an increased mortality at 2 weeks and 6 months after injury in patients administered SOLU-MEDROL compared to placebo.

While a retardant effect on wound healing is seldom encountered, except in high doses, it should be a matter of consideration when SOLU-CORTEF is administered in conjunction with surgery.

SOLU-CORTEF may aggravate diabetes mellitus so that higher insulin dosage may become necessary or manifestation of latent diabetes mellitus may be precipitated.

Since spontaneous remission of some diseases, such as rheumatoid arthritis, may occur during pregnancy, every effort should be made to avoid hormone treatment in pregnancy.

Injection into the deltoid muscle should be avoided because of a high incidence of subcutaneous and muscle atrophy.

Continued supervision of the patient after cessation of SOLU-CORTEF therapy is essential, since there may be a sudden re-appearance of severe manifestations of the disease for which the patient was treated.

If possible, abrupt cessation of corticosteroid therapy should be avoided because of the danger of superimposed adrenocorticoid insufficiency on the infectious process.

Paediatric population

Growth may be suppressed in children receiving long-term glucocorticoid therapy.

The following applies only to the Act-O-Vial (where benzyl alcohol is included in the formulation)

The preservative benzyl alcohol has been associated with serious adverse events, including the “gasping syndrome”, and death in paediatric patients.

The minimum amount of benzyl alcohol at which toxicity may occur is not known. The risk of benzyl alcohol toxicity depends on the quantity administered and the hepatic capacity to detoxify the chemical. Premature and low-birth weight infants are more likely to develop toxicity.

4.5 Interaction with other medicines and other forms of interaction

SOLU-CORTEF is metabolised by 11β-hydroxysteroid dehydrogenase type 2 (11β-HSD2) and the cytochrome P450 (CYP) 3A4 enzyme. The CYP3A4 enzyme catalyses 6β-hydroxylation of steroids, the essential Phase I metabolic step for both endogenous and synthetic corticosteroids. Many other compounds

are also substrates of CYP3A4, some of which have been shown to alter glucocorticoid metabolism by induction (upregulation) or inhibition of the CYP3A4 enzyme.

CYP3A4 inhibitors

May decrease hepatic clearance and increase the plasma concentrations of SOLU-CORTEF. In the presence of a CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin, and grapefruit juice), the dose of SOLU-CORTEF may need to be decreased to avoid steroid toxicity.

CYP3A4 inducers

May increase hepatic clearance and decrease the plasma concentrations of SOLU-CORTEF. In the presence of a CYP3A4 inducer (e.g. rifampicin, carbamazepine, phenobarbital (phenobarbitone), and phenytoin), the dose of SOLU-CORTEF may need to be increased to achieve the desired response.

CYP3A4 substrates

In the presence of another CYP3A4 substrate, the hepatic clearance of SOLU-CORTEF may be affected, with corresponding dosage adjustments required. It is possible that adverse events associated with the use of either medicine alone may be more likely to occur with co-administration.

Non-CYP3A4-mediated effects

Other interactions and effects that occur with SOLU-CORTEF are described in Table 1 below.

Table 1 provides a list and descriptions of the most common and/or clinically important medicine interactions or effects with SOLU-CORTEF.

Table 1. Important medicine or substance interactions/effects with SOLU-CORTEF

Medicine class or type - MEDICINE or SUBSTANCE	*Interaction/effect*
Antibacterial - ISONIAZID	CYP3A4 INHIBITOR (see CYP3A4 inhibitors above for the results of the interaction).
Antibiotic, antitubercular - RIFAMPICIN	CYP3A4 INDUCER (see CYP3A4 inducers above for the results of the interaction).
Anticoagulants (oral)	The effect of SOLU-CORTEF on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulants when given concurrently with corticosteroids. Therefore, coagulation indices should be monitored to maintain the desired anticoagulant effects.
Anticonvulsants - CARBAMAZEPINE	CYP3A4 INDUCER (and SUBSTRATE) (see CYP3A4 inducers and CYP3A4 substrates above for the results of the interaction).
Anticonvulsants - PHENOBARBITAL (PHENOBARBITONE) - PHENYTOIN	CYP3A4 INDUCERS (see CYP3A4 inducers above for the results of the interaction).
Anticholinergics - NEUROMUSCULAR BLOCKERS	Corticosteroids may influence the effect of anticholinergics. 1) An acute myopathy has been reported with the concomitant use of high doses of corticosteroids and anticholinergics, such as neuromuscular blocking drugs (see section 4.4). 2) Antagonism of the neuromuscular blocking effects of all competitive neuromuscular blockers.

Anticholinesterases	Steroids may reduce the effects of anticholinesterases in myasthenia gravis.
Antidiabetics	Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic medicines may be required.
Antiemetic - APREPITANT - FOSAPREPITANT	CYP3A4 INHIBITORS (and SUBSTRATES) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction).
Antifungals - ITRACONAZOLE - KETOCONAZOLE	CYP3A4 INHIBITORS (and SUBSTRATES) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction).
Antivirals - HIV-PROTEASE INHIBITORS	CYP3A4 INHIBITORS (and SUBSTRATES) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction). 1) Protease inhibitors, such as indinavir and ritonavir, may increase plasma concentrations of corticosteroids. 2) Corticosteroids may induce the metabolism of HIV-protease inhibitors resulting in reduced plasma concentrations. Steroids are also known inducers of CYP enzymes in animal models and *in vitro* studies. Dexamethasone, at doses similar to those used in clinical practice, has been shown to increase CYP3A4 activity in both healthy volunteers and human hepatocyte cultures. Therefore, corticosteroids may induce the metabolism of HIV-protease inhibitors by upregulation of CYP3A4.

Aromatase Inhibitors - AMINOGLUTETHIMIDE	Aminoglutethimide-induced adrenal suppression may exacerbate endocrine changes caused by prolonged glucocorticoid treatment.
Calcium channel blocker - DILTIAZEM	CYP3A4 INHIBITOR (and SUBSTRATE) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction).
Cardiac glycosides - DIGOXIN	Concurrent use of corticosteroids with cardiac glycosides may enhance the possibility of arrhythmias or digitalis toxicity associated with hypokalaemia. In all patients taking any of these medicine therapy combinations, serum electrolyte determinations, particularly potassium levels, should be monitored closely.
Contraceptives (oral) - ETHINYLESTRADIOL/ NORETHINDRONE	CYP3A4 INHIBITOR (and SUBSTRATE) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction).
- GRAPEFRUIT JUICE	CYP3A4 INHIBITOR (see CYP3A4 inhibitors above for the results of the interaction).
Immunosuppressant - CICLOSPORIN	CYP3A4 INHIBITOR (and SUBSTRATE) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction). Increased activity of both ciclosporin and SOLU-CORTEF may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.
Immunosuppressant - CYCLOPHOSPHAMIDE - TACROLIMUS	CYP3A4 SUBSTRATES (see CYP3A4 substrates above for the results of the interaction).

Macrolide antibacterial - CLARITHROMYCIN - ERYTHROMYCIN	CYP3A4 INHIBITORS (and SUBSTRATES) (see CYP3A4 inhibitors and CYP3A4 substrates above for the results of the interaction)
Macrolide antibacterial - TROLEANDOMYCIN	CYP3A4 INHIBITOR (see CYP3A4 inhibitors above for the results of the interaction).
NSAIDs (nonsteroidal anti-inflammatory drugs) - high-dose ASPIRIN (acetylsalicylic acid)	1) There may be increased incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with NSAIDs. 2) Corticosteroids may increase the clearance of high-dose aspirin, which can lead to decreased salicylate serum levels. Discontinuation of corticosteroid treatment can lead to raised salicylate serum levels, which could lead to an increased risk of salicylate toxicity.
Potassium-depleting medicines	When corticosteroids are administered concomitantly with potassium-depleting medicines (i.e. diuretics), patients should be observed closely for development of hypokalaemia. There is also an increased risk of hypokalaemia with concurrent use of corticosteroids with amphotericin B, xanthienes, or beta2 agonists. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy and lactation has not been demonstrated.

Some animal studies have shown that corticosteroids, when administered to the mother at high doses, may cause foetal malformations.

SOLU-CORTEF is teratogenic in animals.

Corticosteroids readily cross the placenta. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy must be carefully observed and evaluated for signs of adrenal insufficiency (see section 4.3).

The following applies to the Act-O-Vial (where benzyl alcohol is included in the formulation)

Benzyl alcohol can cross the placenta (see section 4.4).

Breastfeeding

Safety has not been demonstrated.

Corticosteroids are excreted in breast milk.

Fertility

Corticosteroids have been shown to impair fertility in animal studies.

4.7 Effects on ability to drive and use machines

The effect of corticosteroids on the ability to drive or use machinery has not been systematically evaluated. Undesirable effects, such as syncope, vertigo, and convulsions may occur during treatment with corticosteroids. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

The following are typical for all systemic corticosteroids. Their inclusion in this list does not necessarily indicate that the specific event has been observed with this particular formulation.

The following adverse reactions are listed by system organ class and ranked by frequency where possible, using the following convention: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not known (cannot be estimated from the available data).

Adverse reactions table

System organ class	*Frequency*	*Adverse reactions*
Infections and infestations	Common	Masked infections
	Unknown	Opportunistic infection (with any pathogen, in any location in the body, from mild to fatal); infection (becoming active including reactivation of tuberculosis)
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Unknown	Kaposi's sarcoma (has been reported to occur in patients receiving corticosteroid therapy)
Blood and lymphatic system disorders	Not known	Leucocytosis
Immune system disorders	Rare	Hypersensitivity (including anaphylaxis and anaphylactoid reactions [e.g. bronchospasm, laryngeal oedema, urticaria])
	Unknown	May suppress reactions to skin tests
Endocrine disorders	Common	Cushingoid; pituitary-adrenal axis suppression
Metabolism and nutrition disorders	Common	Sodium retention; impaired glucose tolerance; diabetes mellitus
	Uncommon	Fluid retention; hypokalaemic alkalosis

Psychiatric disorders	Uncommon	Psychic derangements/psychotic manifestations (euphoric mood, insomnia, mood swings, personality change, depression, exacerbation of pre-existing affect lability or psychotic behaviour)
Nervous system disorders	Rare	Increased intracranial pressure
	Not known	Spinal epidural lipomatosis with neurological deficits/paraesthesia/paralysis
	Unknown	Benign intracranial hypertension; convulsions
Eye disorders	Uncommon	Cataract subcapsular; exophthalmos
	Not known	Central serous chorioretinopathy with retinal detachment
Cardiac disorders	Unknown	Congestive cardiac failure (in susceptible patients)
Vascular disorders	Common	Hypertension
	Unknown	Venous thrombosis
Respiratory, thoracic and mediastinal disorders	Unknown	Pulmonary embolism; Gasping Syndrome
Gastrointestinal disorders	Uncommon	Peptic ulcer (with possible perforation and haemorrhage); pancreatitis
	Unknown	Gastric haemorrhage; oesophagitis; intestinal perforation
Skin and subcutaneous tissue disorders	Common	Petechiae
	Uncommon	Skin atrophy

	Unknown	Ecchymosis
Musculoskeletal, connective tissue and bone disorders	Common	Osteoporosis; growth retardation
	Uncommon	Osteonecrosis; myopathy; bone fracture
	Unknown	Muscular weakness
Reproductive system and breast disorders	Unknown	Irregular menstruation; amenorrhoea
General disorders and administration site conditions	Uncommon	Impaired healing
Investigations	Common	Decreased carbohydrate tolerance; decreased blood potassium
	Uncommon	Increased intraocular pressure; negative nitrogen balance (due to protein catabolism); increased urine calcium
	Unknown	Increased insulin requirement (or oral hypoglycaemic medicines in diabetics); increased alanine aminotransferase (ALT); increased aspartate aminotransferase (AST); increased blood alkaline phosphatase (ALP)
Injury, poisoning and procedural complications	Uncommon	Tendon rupture (particularly of the Achilles tendon)
	Unknown	Spinal compression fracture

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions 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

4.9 Overdose

There is no clinical syndrome of acute overdosage with SOLU-CORTEF.

Hydrocortisone is dialysable.

Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 21.5 Corticosteroids

Hydrocortisone has metabolic and anti-inflammatory action. After IV injection, pharmacological activity may be evident within one hour and persist for a variable period.

5.2 Pharmacokinetic properties

Excretion of the administered dose is nearly complete within 12 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Monobasic sodium phosphate monohydrate

Dibasic sodium phosphate dried

Benzyl alcohol (preservative) 0,9 % m/v (Act-O-Vial)

Water for injection (Act-O-Vial)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

60 months for 100 mg injection

36 months for 100 mg injection (Act-O-Vial)

60 months for 500 mg injection (Act-O-Vial)

6.4 Special precautions for storage

SOLU-CORTEF 100 mg Injection

Store unreconstituted medicine between 15 °C – 30 °C.

While solutions, when reconstituted as directed, are relatively stable between 15 °C – 30 °C and below, if protected from light, unused solutions prepared with Bacteriostatic Water for Injection or Bacteriostatic Sodium Chloride injections, should be discarded after 3 days.

SOLU-CORTEF 100 mg and 500 mg Act-O-Vial

Store unreconstituted medicine between 15 °C – 30 °C.

While solutions, when reconstituted as directed, are relatively stable between 15 °C – 30 °C and below, if protected from light, unused solutions should be discarded after 3 days.

6.5 Nature and contents of container

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

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

SOLU-CORTEF 100 mg Injection

Preparation of solutions

For intravenous or intramuscular injection, prepare the solution by aseptically adding not more than 2 mL of Bacteriostatic Water for Injection or Bacteriostatic Sodium Chloride Injection to the contents of one vial.

For intravenous infusion, first prepare solution by adding not more than 2 mL of Bacteriostatic Water for Injection to the vial. This solution may then be added to 100 to 1 000 mL of the following: 5 % dextrose in water (or isotonic saline solution or 5 % dextrose in isotonic saline solution if patient is not on sodium restriction).

SOLU-CORTEF Injection, Act-O-Vial system

Directions for using the Act-O-Vial system

1. Press down on plastic activator to force diluent into the lower compartment.
2. Gently agitate to effect solution.
3. Remove plastic tab covering centre of stopper.
4. Sterilise top of stopper with a suitable germicide.
5. Insert needle squarely through centre of plunger-stopper until tip is just visible.
6. Invert vial and withdraw the required dose.

Further dilution is not necessary for intravenous or intramuscular injection.

For intravenous infusion, first prepare the solution as described above. The solution may then be added to 100 to 1 000 mL of 5 % dextrose in water (or isotonic saline solution or 5 % dextrose in isotonic saline solution if patient is not on sodium restriction).

Important

While solutions when reconstituted as directed are relatively stable at 15 °C – 30 °C and below, and if protected from light, unused solutions should be discarded after 3 days.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

8. REGISTRATION/REFERENCE NUMBERS

SOLU-CORTEF 100 mg: G2957 (Act 101/1965)

SOLU-CORTEF 500 mg: G/21.5/201

9. DATE OF FIRST AUTHORISATION

SOLU-CORTEF 100 mg: Not applicable – Old medicine

SOLU-CORTEF 500 mg: 09 April 1975

10. DATE OF REVISION OF THE TEXT

11 August 2022

BOTSWANA: S2

SOLU-CORTEF 100 mg - Reg. No.: B9312150

SOLU-CORTEF 500 mg - Reg. No.: B9312155

NAMIBIA: NS2

SOLU-CORTEF 100 mg - Reg. No.: 14/13.4.1/0441

SOLU-CORTEF 500 mg - Reg. No.: 90/20.1.5/001358

ZIMBABWE: PP

SOLU-CORTEF 100 mg - Reg. No.: 80/21.5.1/1151