PRODUCT INFORMATION

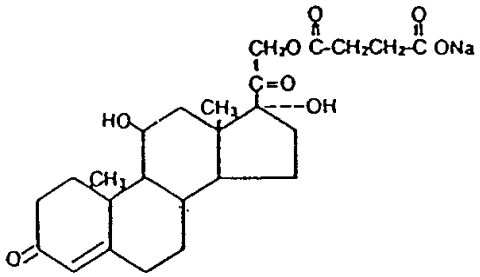
SOLU-CORTEF®

hydrocortisone sodium succinate

NAME OF THE MEDICINE

Non-proprietary name: hydrocortisone sodium succinate

Chemical structure:



The CAS number is 125-04-2 and the molecular weight is 484.52.

DESCRIPTION

Hydrocortisone sodium succinate is a white or nearly white, odourless, hygroscopic amorphous solid. It is very soluble in water and in alcohol, very slightly soluble in acetone and insoluble in chloroform.

SOLU-CORTEF powder for injection is available in several packs for intravenous or intramuscular administration.

100 mg Plain - Vials containing hydrocortisone sodium succinate equivalent to 100 mg hydrocortisone, also 0.8 mg sodium phosphate monobasic (monohydrate), 8.73 mg sodium phosphate dibasic (anhydrous).

ACT-O-VIAL® System Two-Compartment Vial, in three strengths:

	100 mg ACT-O-VIAL Each 2 mL contains (when mixed):	**250 mg ACT-O-VIAL Each 2 mL contains (when mixed):**	**500 mg ACT-O-VIAL Each 4 mL contains (when mixed):**
Hydrocortisone sodium succinate	equivalent to 100 mg hydrocortisone	equivalent to 250 mg hydrocortisone	equivalent to 500 mg hydrocortisone
Sodium phosphate monobasic (anhydrous)	0.8 mg	2 mg	4 mg

Sodium phosphate dibasic (anhydrous)	8.73 mg	21.8 mg	44 mg

When necessary, the pH of each formula was adjusted with sodium hydroxide so that the pH of the reconstituted solution is within the USP specified range of 7 to 8.

PHARMACOLOGY

Pharmacodynamics

Hydrocortisone sodium succinate is an anti-inflammatory adrenocortical steroid. This highly water-soluble sodium succinate ester of hydrocortisone permits the immediate intravenous administration of high doses of hydrocortisone in a small volume of diluent and is particularly useful where high blood levels of hydrocortisone are required rapidly.

Pharmacokinetics

Absorption

Following the intravenous injection of hydrocortisone sodium succinate, demonstrable effects are evident within 1 hour and persist for a variable period. This preparation is also rapidly absorbed when administered intramuscularly. Thus, if constantly high blood levels are required, injections should be made every 4 to 6 hours.

Metabolism

Hydrocortisone sodium succinate has the same metabolic and anti-inflammatory actions as hydrocortisone. When given parenterally and in equimolar quantities, the two compounds are equivalent in biological activity

Excretion

Excretion of the intravenously administered dose is nearly complete within 12 hours. Intramuscular injections are excreted in a pattern similar to that observed after intravenous injections.

INDICATIONS

When oral therapy is not feasible, and the strength, form and route of administration of the drug reasonably lend the preparation to the treatment of the condition, SOLU-CORTEF powder for injection is indicated for intravenous or intramuscular use in the following conditions:

1. Endocrine Disorders

- Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogues may be used in conjunction with mineralocorticoids where applicable; in infancy, mineralocorticoid supplementation is of particular importance). Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; mineralocorticoid supplements may be necessary, particularly when synthetic analogues are used).
- Preoperatively and in the event of serious trauma or illness, in patients with known adrenal insufficiency or when adrenocortical reserve is doubtful
- Shock unresponsive to conventional therapy if adrenocortical insufficiency exists or is suspected

- Congenital adrenal hyperplasia
- Nonsuppurative thyroiditis
- Hypercalcaemia associated with cancer.

2. Rheumatic Disorders

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

- Post-traumatic osteoarthritis
- Synovitis of osteoarthritis
- Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
- Acute and subacute bursitis
- Epicondylitis
- Acute nonspecific tenosynovitis
- Acute gouty arthritis
- Psoriatic arthritis
- Ankylosing spondylitis.

3. Collagen Diseases

During an exacerbation or as maintenance therapy in selected cases of:

- Systemic lupus erythematosus
- Systemic dermatomyositis (polymyositis)
- Acute rheumatic carditis.

4. Dermatological Diseases

- Pemphigus
- Severe erythema multiforme (Stevens-Johnson Syndrome)
- Exfoliative dermatitis
- Bullous dermatitis herpetiformis
- Severe seborrhoeic dermatitis
- Severe psoriasis
- Mycosis fungoides.

5. Allergic States

Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in:

- Bronchial asthma
- Drug hypersensitivity reactions
- Contact dermatitis
- Urticarial transfusion reactions
- Atopic dermatitis
- Serum sickness

- Seasonal or perennial allergic rhinitis
- Acute noninfectious laryngeal oedema (adrenaline is the drug of first choice).

6. Ophthalmic Diseases

Severe acute and chronic allergic and inflammatory processes involving the eye, such as:

- Herpes zoster ophthalmicus
- Iritis, iridocyclitis
- Chorioretinitis
- Diffuse posterior uveitis and choroiditis
- Optic neuritis
- Sympathetic ophthalmia
- Anterior segment inflammation
- Allergic conjunctivitis
- Allergic corneal marginal ulcers
- Keratitis.

7. Gastrointestinal Diseases

To tide the patient over a critical period of the disease in:

- Ulcerative colitis (systemic therapy)
- Regional enteritis (systemic therapy).

8. Respiratory Diseases

- Symptomatic sarcoidosis
- Loeffler's Syndrome not manageable by other means
- Berylliosis
- Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy
- Aspiration pneumonitis.

9. Haematological Disorders

- Acquired (autoimmune) haemolytic anaemia
- Erythroblastopenia (RBC anaemia)
- Idiopathic thrombocytopenic purpura in adults (IV only; IM administration is contraindicated)
- Secondary thrombocytopenia in adults
- Congenital (erythroid) hypoplastic anaemia.

10. Neoplastic Diseases

For palliative management of:

- Leukaemias and lymphomas in adults
- Acute leukaemia in childhood.

11. Oedematous States

- To induce diuresis or remission of proteinuria in the nephrotic syndrome, without uraemia, of the idiopathic type or that due to lupus erythematosus.

12. Nervous System

- Acute exacerbations of multiple sclerosis.

13. Miscellaneous

- Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy
- Trichinosis with neurological or myocardial involvement.

CONTRAINDICATIONS

Systemic fungal infections.

Known hypersensitivity to the drug or any component of the formulation.

Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids (also see **PRECAUTIONS**).

Some Water for Injection may contain benzyl alcohol as a bacteriostatic agent. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants. The SOLU-CORTEF 100 mg plain vial and the 100 mg, 250 mg and 500 mg ACT-O-VIALS **DO NOT** contain benzyl alcohol.

SOLU-CORTEF (hydrocortisone sodium succinate) is not indicated for intrathecal, epidural or local injection, or any other unspecified route of administration.

PRECAUTIONS

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

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

Controlled clinical trials have failed to establish the efficacy of SOLU-MEDROL® (methylprednisolone sodium succinate) in the treatment of sepsis syndrome and septic shock. Two studies suggest that treatment of these conditions with SOLU-MEDROL may increase the risk of mortality in certain patients (i.e. patients with elevated serum creatinine levels or patients who develop secondary infections after receiving SOLU-MEDROL). Although this trial used SOLU-

MEDROL only, Pfizer recommends that SOLU-CORTEF not be used for septic shock or sepsis syndrome either.

Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerve and may enhance the establishment of secondary ocular infections due to fungi or viruses.

Average and large doses of hydrocortisone can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.

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

The use of SOLU-CORTEF powder for injection 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 antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Because rare instances of anaphylactoid reactions (e.g., bronchospasm) have occurred in patients receiving parenteral corticosteroid therapy, appropriate precautionary measures should be taken prior to administration, especially when the patient has a history of allergy to any drug.

Drug-induced secondary adrenocortical insufficiency may be minimised by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy, therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently.

There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex for fear of corneal perforation.

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

The lowest possible dose of corticosteroids should be used to control the condition under treatment and when reduction in dosage is possible, the reduction must be gradual.

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.

Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinaemia (see **INTERACTIONS WITH OTHER MEDICINES**).

Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection, also in diverticulitis, fresh 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.

Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect.

Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

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 drugs (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.

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

Systemic corticosteroids are not indicated for, and should therefore not be used to treat traumatic brain injury. A large multicentre randomised study in patients administered corticosteroid therapy after significant head injury revealed an increased risk of mortality in the corticosteroid group compared to the placebo group.

Effects on Fertility

No specific animal or clinical studies on the effects of hydrocortisone on fertility have been performed. Corticosteroids have been shown to impair fertility and reduce embryonic viability in studies in mice and rats.

Use in Pregnancy

Pregnancy Category C

In animal experiments, corticosteroids have been found to cause malformations of various kinds (cleft palate, skeletal malformations) and abortion. These findings do not seem to be relevant to human beings. Reduced placental and birth weight have been recorded in animals and humans after long-term treatment. Since the possibility of suppression of the adrenal cortex in the newborn baby after long-term treatment must be considered, the needs of the mother must be carefully weighed against the risk to the fetus when prescribing corticosteroids. The short-term use of corticosteroids antepartum for the prevention of respiratory distress syndrome does not seem to pose a risk to the fetus or the newborn infant.

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.

Maternal pulmonary oedema has been reported with tocolysis and fluid overload.

Use in Lactation

Prednisolone is excreted in breast milk, therefore it is reasonable to assume that all corticosteroids are. No specific data are known for hydrocortisone sodium succinate. Therefore, it is recommended that breastfeeding should cease in women who will be or are receiving corticosteroids.

Paediatric Use

Growth and development of infants and children on prolonged corticosteroid therapy should be carefully followed.

Use in Hepatic Impairment

Hydrocortisone may have increased effect in patients with liver diseases since the metabolism and elimination of hydrocortisone is significantly decreased in these patients.

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 are possible after treatment with corticosteroids. If affected, patients should not drive or operate machinery.

INTERACTIONS WITH OTHER MEDICINES

The pharmacokinetic interactions listed below are potentially clinically important.

1. Oral contraceptives retard the metabolism of hydrocortisone due to its increased binding to globulin (transcortin). This increases the plasma levels of hydrocortisone thus potentiating its biological effect.

2. Drugs that induce hepatic enzymes such as phenobarbitone, phenytoin and rifampicin may increase the clearance of corticosteroids and may require increases in corticosteroid dose to achieve the desired response.

3. Drugs such as troleandomycin and ketoconazole may inhibit the metabolism of corticosteroids and thus decrease their clearance. Therefore the dose of corticosteroid should be titrated to avoid steroid toxicity.

4. Corticosteroids may increase the clearance of chronic high dose aspirin. This could lead to decreased salicylate serum levels or increase the risk of salicylate toxicity when corticosteroid is withdrawn. Aspirin should be used cautiously in conjunction with corticosteroids in patients suffering from hypoprothrombinaemia.

5. The effect of corticosteroids on oral anticoagulants is variable. There are reports of enhanced as well as diminished effects of anticoagulant when given concurrently with corticosteroids. Therefore coagulation indices should be monitored to maintain the desired anticoagulant effect.

ADVERSE EFFECTS

Infections and infestations

- Infection masked
- Opportunistic infections (with any pathogen, in any location in the body, from mild to fatal
- Infections (becoming active, including reactivation of tuberculosis)

Neoplasms benign, malignant and unspecified (including cysts and polyps)

- Kaposi's sarcoma (has been reported to occur in patients receiving corticosteroid therapy).

Blood and lymphatic system disorders

- Leucocytosis.

Immune system disorders

- Hypersensitivity (including anaphylaxis and anaphylactoid reactions [e.g., bronchospasm, laryngeal oedema, urticaria])
- Suppression of reactions to skin tests.

Endocrine disorders

- Cushingoid
- Pituitary-adrenal axis suppression, particularly in times of stress, as in trauma, surgery, or illness
- Manifestations of latent diabetes mellitus.

Metabolism and nutrition disorders

- Sodium retention
- Fluid retention
- Alkalosis hypokalaemic
- Glucose tolerance impaired

Psychiatric disorders

- Psychic derangements/psychotic manifestations (euphoric mood, insomnia, mood swings, personality change, depression, exacerbation of pre-existing affect lability or psychotic behaviour).

Nervous system disorders

- Convulsions
- Intracranial pressure increased with papilloedema (pseudotumor cerebri) usually after treatment
- Benign intracranial hypertension
- Epidural lipomatosis
- Vertigo
- Headache.

Eye disorders

- Cataract subcapsular
- Glaucoma
- Exophthalmos
- Central serous chorioretinopathy.

Cardiac disorders

- Congestive heart failure (in susceptible patients).

Vascular disorders

- Thrombosis
- Hypertension.

Respiratory, thoracic and mediastinal disorders

- Pulmonary embolism
- Gasping Syndrome.

Gastrointestinal disorders

- Peptic ulcer (with possible perforation and haemorrhage)
- Gastric haemorrhage
- Pancreatitis
- Oesophagitis
- Intestinal perforation
- Abdominal distension.

Skin & subcutaneous tissue disorders

- Skin atrophy
- Petechiae
- Ecchymoses
- Facial erythema
- Increased sweating.

Musculoskeletal, connective tissue and bone disorders

- Muscle weakness
- Myopathy

- Loss of muscle mass
- Osteoporosis
- Osteonecrosis
- Pathological fracture
- Growth retardation.

Reproductive system and breast disorders

- Menstruation irregular.

General disorders and administration site conditions

- Impaired healing.

Investigations

- Intraocular pressure increased
- Carbohydrate tolerance decreased
- Increased insulin requirement (or oral hypoglycemic agents in diabetics)
- Blood potassium decreased
- Nitrogen balance negative (due to protein catabolism)
- Urine calcium increased
- Alanine transaminase increased (ALT, SGPT), aspartate transaminase (AST, SGOT) increased and blood alkaline phosphatase increased. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation.

Injury, poisoning and procedural complications

- Spinal compression fracture
- Tendon rupture (particularly of the Achilles tendon).

The following additional reactions are related to parenteral corticosteroid therapy:

- Hyperpigmentation or hypopigmentation
- Subcutaneous and cutaneous atrophy
- Sterile abscess.

DOSAGE AND ADMINISTRATION

Infants

Formulations containing benzyl alcohol are contraindicated for use in premature infants (see **CONTRAINDICATIONS**).

Adults

This preparation may be administered by intravenous injection, or by intramuscular injection, the preferred method for initial emergency use being intravenous injection. Following the initial emergency period, consideration should be given to employing a longer acting injectable preparation or an oral preparation.

Therapy is initiated by administering SOLU-CORTEF powder for injection intravenously over a period of 30 seconds (e.g., 100 mg) to 10 minutes (e.g., 500 mg or more). 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 high dose 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.

The initial dose of SOLU-CORTEF powder for injection is 100 mg to 500 mg, depending on the severity of the condition. This dose may be repeated at intervals of 2, 4 or 6 hours as indicated by the patient's response and clinical condition. 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 weight but should not be less than 25 mg daily.

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

Corticoid therapy is an adjunct to, and not a replacement for, conventional therapy.

Dosage Adjustment in Hepatic Impairment

In patients with liver disease, there may be an increased effect of hydrocortisone resulting from decreased metabolism and elimination of the drug. Monitoring the clinical response to hydrocortisone in these patients should be considered (see **PRECAUTIONS**).

Preparation of solutions

100 mg plain vial

For intravenous or intramuscular injection

Prepare solution by aseptically adding **not more than 2 mL** of Bacteriostatic Water for Injections 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 Injections to the vial; this solution may then be added to 100 or 1000 mL of the following: 5% glucose in water (or isotonic saline solution or 5% glucose in isotonic saline solution if patient is not on sodium restriction).

Use in one patient on one occasion only. The 100 mg plain vial and the Act-O-Vials do not contain an antimicrobial agent. Use solution immediately and discard any residue.

Directions for using the ACT-O-VIAL system

1. Tap to ensure that powder is at base of vial and away from the central stopper.

2. Place the Act-O-Vial on a flat, stable surface and hold with one hand.

3. Press down firmly on the plastic activator with the palm of the other hand to force diluent into the lower compartment.

4. Gently mix the solution by turning the vial upside down a number of times. **DO NOT SHAKE THE VIAL.**

5. Remove plastic tab covering centre of stopper.

6. Sterilise top of stopper with a suitable alcohol swab.

7. Whilst vial is on a flat surface, insert needle squarely through centre of stopper until tip is just visible. Invert vial to allow the solution to flow into the top compartment and withdraw the dose.

Further dilution is not necessary for intravenous or intramuscular injection.

For intravenous infusion

First prepare solution as just described. The 100 mg solution may then be added to 100 or 1000 mL of 5% glucose in water (or isotonic saline solution or 5% glucose in isotonic saline solution if patient is not on sodium restriction). The 250 mg solution may be added to 250 to 1000 mL, the 500 mg solution may be added to 500 to 1000 mL of the same diluents. In cases where administration of a small volume of fluid is desirable, 100 mg to 3000 mg of SOLU-CORTEF may be added to 50 mL of the above diluents. The resulting solutions are stable for at least 4 hours and may be administered either directly or by IV piggyback.

To avoid microbial contamination hazards, the further diluted solutions should be used as soon as practicable. If storage is necessary, hold reconstituted/diluted solutions at 2^{o}- 8^{o}C for not more than 24 hours. Any solution not used within 24 hours should be discarded.

When reconstituted as directed, pH's of the solutions range from 7 to 8 and the tonicities are: 100 mg ACT-O-VIAL, 0.36 osmolar, 250 mg ACT-O-VIAL, 500 mg ACT-O-VIAL, 0.57 osmolar (isotonic saline = 0.28 osmolar).

Use diluted/reconstituted solution as soon as possible and only if it is clear. Unused solution may be stored at 2^{o}- 8^{o}C for not more than 24 hours provided aseptic procedures are followed. Any solution not used within 24 hours should be discarded.

OVERDOSAGE

Symptoms and Signs

Reports of acute toxicity and metabolic disturbances with glucocorticoids are rare but do occur. There is no clinical syndrome of acute overdosage with hydrocortisone sodium succinate. Acute overdose may possibly aggravate pre-existing disease states such as ulceration of the gastrointestinal tract, electrolyte disturbances, infections, diabetes and oedema.

Repeated frequent doses (daily or several times per week) over a protracted period may result in a Cushingoid state. The possibility of adrenal suppression should be guarded against by gradual diminution of dose levels over a period of time.

Treatment

In the event of acute overdose, treatment is symptomatic and supportive, including respiratory and cardiovascular function. In chronic toxicity, fluids and electrolytes should be monitored closely. Serum levels are not clinically useful.

Contact the Poisons Information Centre on 13 11 26 for advice on the management of an overdose.

PRESENTATION AND STORAGE CONDITIONS

Presentation

SOLU-CORTEF Powder for Injection is available in the following packages:

5 x 100 mg Plain Vial

1 x 100 mg ACT-O-VIAL 2 mL

1 x 250 mg ACT-O-VIAL 2 mL

1 x 500 mg ACT-O-VIAL 4 mL.

Storage Conditions

Store unreconstituted powder below 25°C; protect from light.

NAME AND ADDRESS OF THE SPONSOR

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
WEST RYDE NSW 2114

POISON SCHEDULE

S4, Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

100 mg Plain Vial: 2 August 1991

100 mg, 250 mg, 500 mg Act-O-Vials: 5 March 2010.

DATE OF MOST RECENT AMENDMENT

28 November 2014

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