

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Solu-Cortef® 100 mg Powder for Solution for Injection or Infusion hydrocortisone (as sodium succinate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- **Solu-Cortef is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor – you may need to reduce the dose gradually.
- **Solu-Cortef can cause side effects in some people** (read section 4. Possible side effects). Some problems such as mood changes (feeling depressed, or “high”), or stomach problems can happen straight away. If you feel unwell in any way, keep taking Solu-Cortef, but **see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a round face (read section 4. Possible side effects for more information).
- **If you take it for more than 3 weeks, you will get a blue “steroid card”**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away**.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 Solu-Cortef is given to you
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 contains hydrocortisone sodium succinate.

Hydrocortisone belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body and help maintain health and well-being.

Boosting your body with extra corticosteroid such as Solu-Cortef is an effective way to treat various illnesses involving inflammation of the body. Solu-Cortef reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Corticosteroids can also help treat hypersensitivity (**anaphylactic**) reactions or other stressful conditions. These include inflammatory or allergic conditions affecting the:

- **bowel and gut** e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel),
- **lungs** e.g. bronchial asthma or inflammation caused by breathing in (aspirating) vomit or stomach contents,
- **skin** e.g. Stevens-Johnson syndrome (an auto-immune disorder in which the immune system causes the skin to blister and peel), or systemic lupus erythematosus (lupus).

Solu-Cortef may be prescribed to treat conditions other than those listed above, such as adrenal insufficiency and other medical emergencies like treatment of shock associated with this.

You must talk to a doctor if you do not feel better or if you feel worse or are unsure why you have been given this medicine.

2. What you need to know before you are given Solu-Cortef

Do not use Solu-Cortef:

- If you think you have ever suffered an **allergic reaction** (hypersensitivity), or any other type of reaction to Solu-Cortef, any other medicine containing a corticosteroid or any of the other ingredients of this medicine (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 any fungal **infection** (such as thrush).
- If you have recently had, or are about to have any **vaccination**.

This medicine should not be injected:

- Into the spinal cord (intrathecal) [except as part of certain chemotherapy regimens], or by the epidural route.

Children:

Solu-Cortef should be carefully administered in children as prolonged use interferes with the growth and development of the child and can cause cataracts in children.

See your doctor immediately if any of the above apply to you.

Warnings and precautions

Talk to your doctor or nurse before taking this medicine if you have any of the following conditions.

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

- **Chickenpox, shingles or a herpes** eye infection. If you think you have been in contact with someone with chickenpox or shingles and you have not already had these illnesses, or if you are unsure if you have had them.
- **Severe depression or manic depression** (bipolar disorder). This includes having depression before or while taking steroid medicines like Solu-Cortef, or **if any of your close family** has had these illnesses.
- If you suffer from mood swings, sleeplessness and personality changes.
- If you are under unusual **stress**.
- If you develop **adrenal insufficiency**.

- **Cushing's Syndrome** (a hormone disorder caused by high levels of cortisol in the blood).
- **Diabetes** (or if there is a family history of diabetes).
- **Epilepsy, fits or seizure.**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- **Cataract.**
- Contact your doctor if you experience **blurred vision or other visual disturbances.**
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure).
- **Fluid retention in the body.**
- **Hypothyroidism** (an under-active thyroid).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **Joint infection.**
- **Kidney or liver disease.**
- **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past.
- **Myasthenia gravis** (a condition causing tired and weak muscles).
- **Osteoporosis** (brittle bones – bones that break easily).
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- **Skin abscess.**
- **Stomach ulcer, diverticulitis** (inflammation of the bowel wall) or other serious stomach or intestinal problems.
- **Thrombophlebitis** - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins).
- **Traumatic brain injury.**
- **Tuberculosis** (TB) or if you have suffered tuberculosis in the past.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using hydrocortisone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with hydrocortisone. You may need additional treatment to alleviate this condition.

Tumour lysis syndrome can occur when corticosteroids are used during cancer treatments. Tell your doctor if you have cancer and have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances and shortness of breath.

If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Caution should be exercised with corticosteroids as they can cause an eye condition (central serous chorioretinopathy) where a collection of fluid forms under the light-sensitive layer of tissue at the back of the inner eye (retina) causing visual impairment and may lead to retinal detachment.

Long term therapy of corticosteroids in high doses can cause an abnormal amount of fat deposition on or outside the lining of the spine (epidural lipomatosis).

Tell your doctor if you suspect an infection has occurred, as corticosteroids are known to increase susceptibility to infections and may mask their signs.

Hydrocortisone treatment may increase your susceptibility to different infections, make current infections worse, or cause old, hidden infections to return or get worse. New infections may also appear during hydrocortisone use. Different infections may therefore occur more easily during treatment. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Oral anticoagulants (medicines taken by mouth to prevent blood clotting) if used together with Solu-Cortef can increase your risk of bleeding. In some instances, the effect of the oral anticoagulants may also be reduced. Your doctor may need to frequently monitor your bleeding risk by running additional blood test, while you are treated with Solu-Cortef. They may also adjust your Solu-Cortef dose if needed.

This medicine is not recommended for use by the intrathecal route of administration.

Other medicines and Solu-Cortef

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following medicines which can affect the way Solu-Cortef or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy.
- **Oral anticoagulants** - medicines taken by mouth to prevent blood clotting.
- **Anticholinergics** - medicines called neuromuscular blocking agents which are used in some surgical procedures.
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine.
- **Antibacterial** - such as isoniazid, erythromycin, clarithromycin, troleandomycin.
- **Antidiabetics** - medicines used to treat high blood sugar.
- **Antiemetic** - such as **Aprepitant** and **Fosaprepitant** used to prevent nausea and vomiting.
- **Antifungal** - Ketoconazole or itraconazole.
- **Antitubercular** - Rifampin and rifabutin – antibiotics used to treat tuberculosis (TB).
- **Antiviral** - used to treat HIV infections.
- **Aromatase Inhibitor** - Aminoglutethimide – used for treating cancer.
- **NSAIDs - Aspirin** (high dose) and non-steroidal anti-inflammatory medicines such as ibuprofen used to treat mild to moderate pain.
- **Antiepileptics/Anticonvulsants** - Barbiturates, carbamazepine, and phenytoin – used to treat epilepsy.
- **Carbenoxolone** - used for heartburn.
- **Ciclosporin** - used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant.
- **Calcium Channel Blocker** - Diltiazem.
- **Cardiac Glycosides** - Digoxin - used for heart failure and/or an irregular heart beat.
- **Immunosuppressant** - Tacrolimus and cyclophosphamide – used following an organ transplant to prevent rejection of the organ.
- **Neuroblocking agents** - pancuronium which are used in some surgical procedures.
- **Oral contraceptive** - Estrogen containing products.
- **Pharmacokinetic boosters - Cobicistat** - containing products.
- **Potassium depleting agents** - such as diuretics (sometimes called water tablets), **amphotericin B**, xanthenes or beta₂ agonists (e.g. medicines used to treat asthma).

- **Vaccines** - tell your doctor or nurse if you have recently had, or about to have, any vaccination. You **must not** have 'live' vaccines while using this medicine. Other vaccines may be less effective.
- **Grapefruit juice.**

If you are taking long term medication(s)

If you are being treated for diabetes, high blood pressure or water retention (oedema) tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operation tell your doctor, dentist or anaesthetist that you are taking this medicine.

If you require a test to be carried out by your doctor or in hospital it is important that you tell the doctor or nurse that you are taking Solu-Cortef. This medicine can affect the results of some tests.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine because it could slow the baby's growth. Corticosteroids can cross the placenta which is a risk associated with low birth weight of the baby.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

Tell your doctor if you are breast-feeding as small amounts of corticosteroid medicines may get into breast milk. If you continue breast-feeding while you are having treatment, your baby will need extra checks to make sure he or she is not being affected by your medicine.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

The effect of this class of medicines on the ability to drive or use machinery has not been studied. There are undesirable effects observed with the use of this medicine such as convulsions (seizures). If you are affected you should not drive or operate machinery.

Solu-Cortef contains sodium

This medicine contains 10.1 mg of sodium (main component of cooking/table salt). This is equivalent to 0.5% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Solu-Cortef is given to you

If you are admitted to hospital for any reason always tell your doctor or nurse that you are taking this medicine. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

Dosage information

Your doctor will decide on the site of injection, how much of the medicine 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. Your doctor may also want you to take a second type of steroid or a salt supplement to help your salt balance.

Adults

Solu-Cortef will be given as an injection by your doctor or nurse, either into a vein (intravenous) or into a muscle (intramuscular). Usually the first dose is given into a vein, especially in an emergency.

It will be given slowly over a period of between 1 – 10 minutes. Depending on your condition a repeat dose may be injected at intervals of between 2 to 6 hours. Large doses should normally be used for only two to three days.

The medicine is first dissolved in sterile water for injections. If the medicine is to be given by infusion (using a pump or drip) it is then mixed with another suitable fluid. No other medicines should be mixed with it.

Elderly

Treatment will normally be the same as for younger adults. However your doctor may want to see you more regularly to check how you are getting on with this medicine.

Children and adolescents

Corticosteroids can affect growth in children so your doctor will prescribe the lowest dose (not less than 25 mg a day) that will be effective for your child.

If you are given more Solu-Cortef than you should

If you think you have been given too many injections of this medicine please speak to your doctor immediately.

Stopping/reducing the dose of your Solu-Cortef

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

You will need to come off this treatment slowly if you:

- have been given corticosteroids, such as Solu-Cortef, for a long time,
- have been given high doses of corticosteroids, such as Solu-Cortef,
- have already had a course of corticosteroid tablets or injections in the last year,
- already have problems with your adrenal glands (adrenocortical insufficiency) before you start this treatment.

You will need to come off this medicine slowly to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, sweating and weight loss.

If your symptoms seem to return or get worse as your dose of this medicine is reduced tell your doctor immediately.

Mental problems while taking Solu-Cortef

Mental health problems can happen while taking steroids like Solu-Cortef (see also section 4, Possible side effects).

- These illnesses can be serious.
 - Usually they start within a few days or weeks of starting the medicine.
 - They are more likely to happen at high doses.
 - Most of these problems go away if the dose is lowered or the medicine is stopped.
- However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone **taking** this medicine) 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.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. Your doctor will have given you this medicine for a condition which if not treated properly could become serious.

In certain medical conditions medicines like Solu-Cortef (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek immediate attention. Your doctor will then decide whether you should continue taking your medicine.

- **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.
- **Acute pancreatitis**, stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- **Ulcers or bleeding ulcers**, symptoms of which are severe stomach pain which may go through to the back and could be associated with bleeding from the back passage, black or bloodstained stools and/or vomiting blood.
- **Infections**. This medicine 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. This medicine may also make you more likely to develop a severe infection. It can also increase your susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.
- **Pulmonary embolus** (blood clot in the lung) symptoms include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull** of children (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.

If you experience any of the following side effects, or if you notice any other unusual effects not listed in this leaflet, tell your doctor straight away.

The frequency of the side effects is not known. The frequency cannot be estimated from the available data.

Blood, heart and circulation

- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing.
- High blood pressure (hypertension), symptoms of which are headaches, or generally feeling unwell.
- Increased numbers of white blood cells (leucocytosis).
- Low blood pressure.
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

Body water and salts

- Swelling and high blood pressure, caused by increased levels of water and salt content.
- Swelling of the extremities of the body e.g. ankles.
- Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

Digestive system

- Nausea (feeling sick) or vomiting (being sick).
- Ulcers or thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Bloating stomach.
- Abdominal pain.
- Diarrhoea.

Ears

- A feeling of dizziness or spinning (vertigo).

Eyes

- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (causing a condition called papilloedema, and which may cause sight disturbance).
- Damage to the optic nerve or cataracts (indicated by failing eyesight).
- Thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera).
- Worsening of viral or fungal eye infections.
- Protruding of the eyeballs (exophthalmos).
- Visual impairment such as a blind spot, decreased or blurry vision and distortion of shapes, caused by a collection of fluid under the tissue lining at the back of the eye (retina).
- Blurred vision.

General disorders

- Feeling tired or unwell.
- Skin reactions at the site of injection.

Hormones and metabolic system

- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Irregular or no periods in women.
- Round or moon-shaped face (Cushingoid facies).
- Appetite and weight increased.
- Diabetes or worsening of existing diabetes.
- Prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months.
- Blood urea increased.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in your body may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after your medicine has cleared naturally from your system. You will not notice any symptoms if this happens, but it will show up if you have a blood test.
- Drug withdrawal syndrome includes symptoms like runny nose, fever, headache, loss of appetite, tiredness, joint pain, peeling of skin, weight loss and low blood pressure.
- Abnormal level of fats e.g. cholesterol in the blood.
- Abnormal fat deposition in the body.

Muscles and bones

- Muscle pain.
- Muscle weakness or wasting.

- Brittle bones (bones that break easily).
- Broken bones or fractures.
- Breakdown of bone and joint due to poor circulation of blood, this causes pain in the hip.
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps or spasms.

Nerves and mood issues

Steroids, including Solu-Cortef, can cause serious mental health problems.

These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Solu-Cortef.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory.

Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone. If you notice any of these problems **talk to a doctor straight away**.

Other nervous system side effects may include:

- Convulsions (seizures), dizziness, drowsiness, difficulty breathing, irritability, sensation of cold, heat or numbness, tinnitus or unconsciousness.
- Headache.
- Back pain, decreased strength or sensation in the legs or imbalance, caused by a buildup of fat within the spinal canal (epidural lipomatosis).

Skin

- Abscess, especially near injection sites.
- Acne.
- Poor wound healing.
- Thinning of skin with stretch marks.
- Stretch marks (skin striae).
- Bruising.
- Small purple/red patches on the skin.
- Pale or darker patches on your skin, or raised patches which are an unusual colour.
- Excessive growth of bodily and facial hair.
- Rash, itching, hives.
- Increased sweating.
- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis has been reported following dose reduction or discontinuation of long term, high dose treatment. Most cases resolve spontaneously.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Solu-Cortef

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. Do not store this medicine above 25°C. Once the medicine has been mixed with sterile water for injections the solution should be used straight away. Any unused liquid should be disposed of safely. Your doctor will check that the solution contains no particles and is not discoloured before using it.

6. Contents of the pack and other information

What Solu-Cortef contains

The active substance is hydrocortisone sodium succinate. Each vial of this medicine contains 133.7 mg of hydrocortisone sodium succinate (equivalent to 100 mg hydrocortisone).

The other ingredients are disodium phosphate anhydrous, sodium dihydrogen phosphate and sodium hydroxide (see section 2 “Solu-Cortef contains sodium”).

What Solu-Cortef looks like and contents of the pack

Solu-Cortef is a white powder for solution for injection or infusion. It is packaged in 10 vial packs containing 10 vials of powder for solution for injection or infusion.

Marketing Authorisation Holder

Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road, Dublin 4, D04 K7N3, Ireland.

Manufacturer

Pharmacia NV/SA, Rijksweg 12, B-2870, Puurs, Belgium.

Company Contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road,
Dublin 4, D04 K7N3, Ireland.
Telephone 1800 633 363

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The following information is intended for healthcare professionals only

Solu-Cortef® 100 mg Powder for Solution for Injection or Infusion
Hydrocortisone as sodium succinate
PFIZER

Powder for solution for injection or infusion

For further information, consult the SPC (Summary of Product Characteristics).

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 being intravenous injection. Following the initial emergency period, consideration should be given to employing a longer-acting injectable preparation or an oral preparation.

Dosage usually ranges from 100 mg to 500 mg depending on the severity of the condition, administered by intravenous injection over a period of one to ten minutes.

This dose may be repeated at intervals of 2, 4 or 6 hours as indicated by the patient's response and clinical condition.

Dosage requirements are variable and must be individualized on the basis of the disease under treatment, its severity and the response of the patient over the entire duration of treatment. A risk/benefit decision must be made in each individual case on an ongoing basis.

The proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage, which will maintain an adequate clinical response, is reached.

In general high-dose corticosteroid therapy should be continued only until the patient's condition has stabilised - usually not beyond 48 to 72 hours. If hydrocortisone therapy must be continued beyond 48 to 72 hours hyponatraemia may occur, therefore it may be preferable to replace Solu-Cortef with a corticosteroid such as methylprednisolone sodium succinate as little or no sodium retention occurs.

If after long-term therapy the drug is to be stopped, it needs to be withdrawn gradually rather than abruptly (see section 4.4 of the SPC).

Undesirable effects may be minimised by using the lowest effective dose for the minimum period (see section 4.4 of the SPC).

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

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

Elderly patients: Solu-Cortef is primarily used in acute short-term conditions. There is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients should be planned bearing in mind the more serious consequences of the common side-effects of corticosteroids in old age and close clinical supervision is required (see section 4.4 of the SPC).

Paediatric population: Dosage should be reduced for infants and children, but should be governed more by the severity of the condition and response of the patient than by age or size. Dosage should not be less than 25 mg daily (see section 4.4 of the SPC).

This medicine is not recommended for use by the intrathecal route of administration.

Preparation of solutions: For intravenous or intramuscular injection prepare the solution aseptically by adding not more than 2 ml of sterile water for injections to the contents of one vial of Solu-Cortef 100 mg, shake and withdraw for use.

For intravenous infusion, first prepare the solution by adding not more than 2 ml of sterile water for injections to the vial; this solution may then be added to 100 ml – 1000 ml (but not less than 100 ml) of 5% dextrose in water (or isotonic saline solution or 5% dextrose in isotonic saline solution if patient is not on sodium restriction).

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 of the SPC.

When reconstituted as directed the pH of the solution will range from 7.0 to 8.0.

Shelf-life

The shelf life is printed on labels and cartons. Do not use Solu-Cortef after this date. After reconstitution with sterile water for injections, use immediately, discard any remainder.

Storage of the product

Do not store above 25°C. Refer to Posology and method of administration section above.

Reconstituted solutions should be used immediately. No diluents other than those referred to are recommended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Use solution only if it is clear.