What is in this leaflet

Please read this leaflet carefully before being treated with SOLUCORTEF. This leaflet answers some common questions about SOLUCORTEF.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with SOLUCORTEF against the benefits they expect it will have for you.

If you have any concerns about being treated with this medicine, ask your doctor or pharmacist.

Keep this leaflet even after your treatment with SOLUCORTEF is finished. You may need to read it again.

What SOLUCORTEF is used for

SOLUCORTEF acts by reducing inflammation (pain, swelling, redness and heat).

SOLUCORTEF is an injection. It is used when oral treatment is not possible. Hydrocortisone sodium succinate, the active ingredient in SOLUCORTEF, belongs to a group of medicines called corticosteroids.

Your doctor has prescribed SOLUCORTEF for the treatment of one or more of the following:

- certain glandular disorders
- rheumatic disorders

- skin diseases
- allergic conditions
- inflammation of the eyes
- stomach or gut disorders
- respiratory diseases
- blood disorders
- multiple sclerosis.

Your doctor may have prescribed SOLUCORTEF for another reason.

Ask your doctor if you have any questions about why SOLUCORTEF has been prescribed for you.

SOLUCORTEF is available only with a doctor's prescription.

SOLUCORTEF is not addictive.

Before being treated with SOLUCORTEF

The following factors should be considered before being treated with SOLUCORTEF.

When SOLUCORTEF must not be given

SOLUCORTEF must not be given if you:

- are allergic to SOLUCORTEF, other medicines containing hydrocortisone sodium succinate or any ingredient listed at the end of this leaflet
- have a systemic fungal infection.

SOLUCORTEF must not be injected into the spinal cord (intrathecal or epidural) or by any other unapproved route of administration.

SOLUCORTEF must not be used after the expiry date (Exp.) printed on the carton has passed.

Before treatment with SOLUCORTEF

Tell your doctor if you are allergic to any other medicines or any other substances such as foods, preservatives and dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using SOLUCORTEF when pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using SOLUCORTEF when breastfeeding.

Tell your doctor if you have or have had any medical conditions, especially the following:

- stomach or gut disorders
- high blood pressure (hypertension)
- tuberculosis
- herpes simplex of the eye
- mental or mood disorders
- thin or weak bones that tend to break easily (osteoporosis)
- myasthenia gravis (ongoing chronic fatigue and muscle weakness)
- underactive thyroid gland
- kidney or liver disease
• ulcerative colitis (disease of the bowel)
• diabetes or increased sugar in your blood.

Tell your doctor if you plan to have surgery.
If you have not told your doctor about any of the above, tell them before you are treated with SOLU-CORTF.

Taking other medicines
Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking:
• oral contraceptives
• anticonvulsants, e.g. phenytoin, phenobarbitone
• antifungal agents, e.g. ketoconazole
• rifampicin (an antibiotic)
• aspirin
• oral medicines to reduce blood clotting, e.g. warfarin.

Ask your doctor or other healthcare professional if you are not sure about this list of medicines.

How much is given
You may be given a single dose or several doses 2 to 6 hours apart.

The dose and frequency of SOLU-CORTF that your doctor prescribes for you depends on your medical condition. Your doctor may change the dose and how many times a day you have it, as your condition changes.

Tell your doctor if you have liver disease as your doctor may need to monitor your response and/or adjust your dose.

How long it is given
Your doctor will continue giving you SOLU-CORTF for as long as your condition requires or before changing to another similar medicine that can be given less frequently or taken orally.

If you are given too much (overdose)
Overdose is unlikely as treatment will be given by your doctor. The possible effects of overdose are the same as those listed under Side Effects.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have been given too much SOLU-CORTF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the SOLU-CORTF box or this leaflet available to give details if needed.

While being treated with SOLU-CORTF

Things you must do
Tell any other doctors, dentists and pharmacists who are treating you that you are being treated with SOLU-CORTF.

If you are about to be given a vaccine or started on any new medicine, tell your doctor, dentist or pharmacist that you are being treated with SOLU-CORTF.

If you become pregnant while having treatment with SOLU-CORTF tell your doctor.

SOLU-CORTF may hide some of the signs of an infection. If you get an infection or suspect an infection during a course of treatment tell your doctor as soon as possible.

If you are a diabetic, your need for insulin or glucose lowering medicines may increase while being treated with SOLU-CORTF.

Side effects
Tell your doctor or pharmacist as soon as possible if you do not feel well while being treated with SOLU-CORTF.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Ask your doctor or other healthcare professional to answer any questions you may have.

Children
Diluents that contain benzyl alcohol should not be used with SOLU-CORTF to treat children.
Some diluents used with your medicine may contain the preservative benzyl alcohol. Benzyl alcohol has been associated with serious side effects in newborns (especially premature and low weight infants) which can be fatal.

Growth in children may be affected by treatment with SOLU-CORTEF so your doctor may also monitor your child's height.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- fluid retention (causes an increase in weight)
- muscle weakness or loss of muscle mass
- increased sweating
- headache or dizziness
- effects on your menstrual periods
- mood changes e.g. overexcitement, depression, suicidal thoughts, hallucinations, anxiety
- itchy skin
- thin fragile skin, bruising or change in skin colour
- facial redness
- excessive thirst, the passing of an increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell
- problems with your growth.

If these effects do not go away or they are worrying to you, tell your doctor.

Tell your doctor immediately or go to Accident & Emergency at your nearest hospital if you experience any of the following:

- Allergic reactions, e.g. skin rash, itching, difficulty breathing, wheezing or coughing
- bone fractures or muscle pain
- severe stomach pain, nausea and vomiting
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea
- convulsions or fits
- blurred or distorted vision or loss of vision, eye infections
- red, purple or brown patches on your skin
- problems with your back, including pain or weakness
- loss of sensation or problems with your reflexes (slow or too fast)
- bouts of anxiety and headaches, sweating, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurring vision, stomach pains, and raised blood pressure. These could be symptoms of a rare tumour of the adrenal gland, which sits near the kidney.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

SOLU-CORTEF may also cause chemical imbalances in the blood and urine, swelling of the pancreas (pancreatitis), bleeding in the stomach, masking of infections, increased risk of infection, hormone changes, metabolic changes, changes in liver enzymes, or increased blood pressure. Some of these side effects can only be found when your doctor does tests to check on your progress.

This is not a complete list of all possible side effects. Some people may get other side effects while being treated with SOLU-CORTEF.

It is very important to tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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After treatment with SOLU-CORTEF

Storage

SOLU-CORTEF will normally be stored in a hospital. The undiluted product should be stored below 25°C and should be protected from light (kept in the packaging before use).

The diluted/reconstituted solution should be used as soon as possible and only if it is clear. If storage is necessary, hold reconstituted diluted solutions at 2°C - 8°C for not more than 24 hours. Any solution not used within 24 hours should be discarded.

Product description

What SOLU-CORTEF looks like

SOLU-CORTEF powder for injection is a white, or nearly white powder in a vial. Vials are also available which have separate sections containing the powder and the liquid to dissolve the powder ready for injection (ACT-O-VIAL system).

SOLU-CORTEF 100 mg Plain Vial is supplied in packs of 5 vials.
SOLU-CORTEF ACT-O-VIALS 100 mg, 250 mg and 500 mg are supplied in packs of 1 vial.

Identification

SOLU-CORTEF (hydrocortisone sodium succinate) can be identified by an Australian Register Number which is found on the carton.

- Plain vial (powder only):
  100 mg: AUST R 12264
- ACT-O-VIAL® (powder and diluent):
  100 mg: AUST R 167893
  250 mg: AUST R 167894
  500 mg: AUST R 167895.
Ingredients

SOLU-CORTEF contains hydrocortisone sodium succinate as the active ingredient.

Each vial also contains the following inactive ingredients:
- sodium phosphate monobasic
- sodium phosphate dibasic.

The diluent for the ACT-O-VIALs consists of Water for Injections. It does not contain an antimicrobial preservative. Use in one patient on one occasion only.

Supplier

SOLU-CORTEF is supplied in Australia by:

**Pfizer Australia Pty Ltd**

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia.

Toll free number: 1800 675 229.

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