What is in this leaflet

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

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 SOLU-CORTEF 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 SOLU-CORTEF is finished.

You may need to read it again.

What SOLU-CORTEF is used for

SOLU-CORTEF acts by reducing inflammation (pain, swelling, redness and heat).

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

Your doctor has prescribed SOLU-CORTEF for the treatment of one or more of the following:

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

Your doctor may have prescribed SOLU-CORTEF for another reason.

Ask your doctor if you have any questions about why SOLU-CORTEF has been prescribed for you.

SOLU-CORTEF is available only with a doctor's prescription.

SOLU-CORTEF is not addictive.

Before being treated with SOLU-CORTEF

The following factors should be considered before being treated with SOLU-CORTEF.

When SOLU-CORTEF must not be given

SOLU-CORTEF must not be given if you:

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

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

Before treatment with SOLU-CORTEF

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.

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

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)

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-CORTEF.

**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 health care professional if you are not sure about this list of medicines.

**How SOLU-CORTEF is given**

You will not usually be handling this product directly. It will be given to you as an injection by an experienced health care professional.

SOLU-CORTEF is given as an injection into a muscle or slowly into a vein over a period of 30 seconds to 10 minutes depending on the dose required.

Instructions for the preparation of solutions for the 100 mg vial or the directions for using the Act-O-Vial system are included in the package insert.

**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-CORTEF 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-CORTEF 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-CORTEF. 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-CORTEF box or this leaflet available to give details if needed.

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**Side effects**

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

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 health care professional to answer any questions you may have.

**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
- itchy skin
- thin fragile skin, bruising or change in skin colour
- facial redness

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
• convulsions or fits
• blurred vision or loss of vision

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.
Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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.

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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