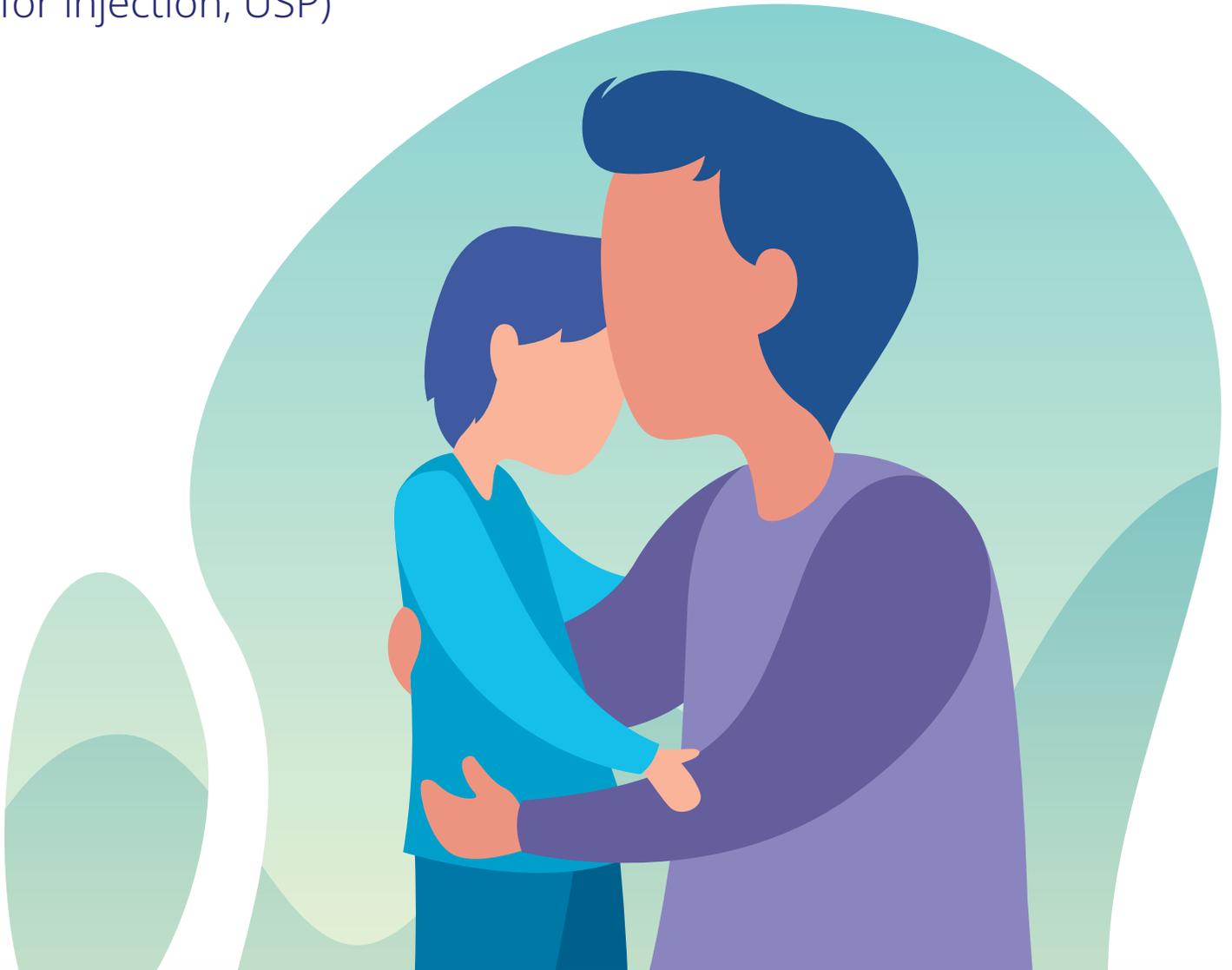


Taking care of a loved one with  
adrenal insufficiency (AI)

# Solu-Cortef<sup>®</sup>

(hydrocortisone sodium succinate  
for injection, USP)



Scan the QR Code to view the ACT-O-VIAL<sup>®</sup> Instructions for Use video on PfizerPro, or visit <https://www.pfi.sr/howtouse-act-o-vial-system>. Or, search “How to use the ACT-O-VIAL System” on YouTube, to watch the Instructions for Use video on the Pfizer Ready-To-Use channel.

Please see full [Prescribing Information here](#) and Important Safety Information on pages 7-8.

## Answers to your questions about AI

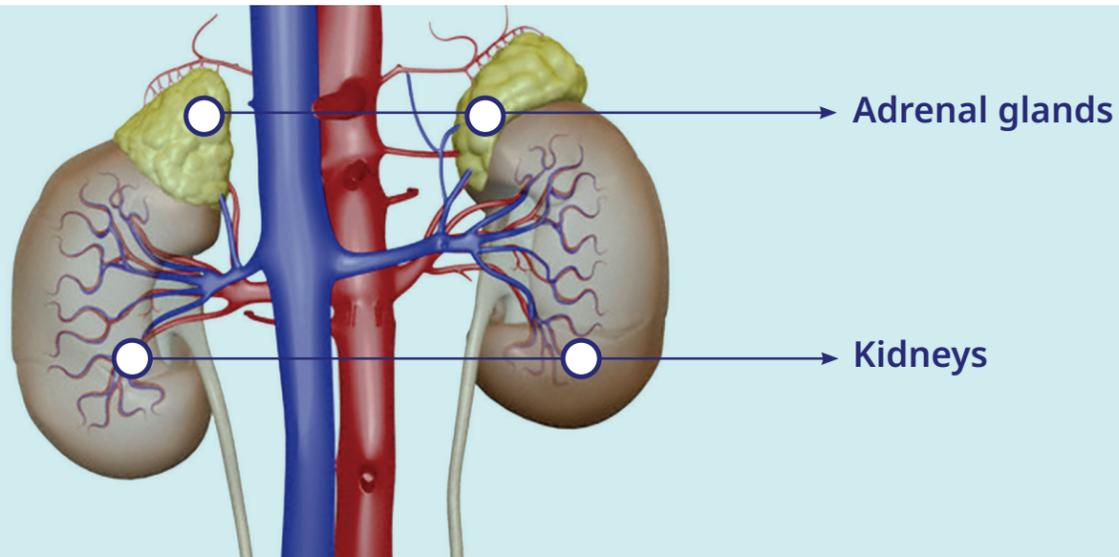
### What is Adrenal Insufficiency (AI)?

AI happens when the adrenal glands do not make enough of certain hormones.

In some people, AI can affect stress response and the ability to maintain other essential life functions.

### What are the adrenal glands?

They are 2 small glands above the kidneys. They secrete many hormones that the body needs, such as cortisol (core-tih-sawl) and aldosterone (al-doss-tur-own).



### Why does the body need these hormones?

- **Cortisol** helps the body use sugar for energy. It also helps the body get well after stress
- **Aldosterone** helps the body keep the right balance of salt and potassium (minerals), and water

Please see full [Prescribing Information here](#) and additional Important Safety Information on pages 7-8.

### Is AI serious?

Yes, it can be life-threatening, but it can be treated.

### What causes AI?

Long-term AI can be caused by

- Addison's disease
- Surgical removal of the pituitary gland
- Surgical removal of the adrenal glands
- A genetic defect of the adrenal glands

AI can also be caused by

- Physical stress (including illness, serious injury, surgery)
- Infection
- High doses of steroids
- Some types of complicated surgery

### How can you tell if someone has AI?

People who have AI do not feel well. They may have 1 or more of the following symptoms:

- Chronic or long-lasting fatigue
- Muscle weakness
- Loss of appetite
- Weight loss
- Abdominal pain

### Selected Important Safety Information

Solu-Cortef should not be used in patients with systemic fungal infections or in patients who are allergic to any of its ingredients. Severe reactions might occur.

Solu-Cortef should not be used in patients with idiopathic thrombocytopenic purpura, a condition that causes low platelets and may result in increased bleeding.

Solu-Cortef should not be injected into the spinal cord area because it is not approved for this use. Serious events such as paralysis, stroke, blindness, and even death have been reported.

## Answers to your questions about AI

### Are there other symptoms of untreated AI?

Untreated AI may cause

- Nausea
- Vomiting
- Diarrhea
- Low blood pressure that drops further when you stand up, causing dizziness or fainting
- Irritability and depression
- Joint pain
- Craving salty foods
- Low blood sugar
- Darkened skin (seen in people with Addison's disease)

AI symptoms may come on slowly over time, so they may be overlooked or confused with other illnesses.

Call your doctor at once if

- You or your loved one have any of the symptoms listed above
- You think you or your loved one has AI
- If you or your loved one always feel tired, weak, or experience weight loss

### How is AI treated?

People with AI must take medicine each day to replace the hormones that their bodies are not making. This medicine is called a "replacement dose."

A doctor may prescribe pills called hydrocortisone (high-dro-core-tih-zone), dexamethasone (deck-suh-meth-uh-zone), or prednisone (predd-nih-zone).

Children often take hydrocortisone liquid instead of pills. They should take their AI medicines every day, just as the doctor instructs.

People with AI who can't keep the right amounts of salt and fluids in their body are given a medicine called fludrocortisone (flew-dro-core-tih-zone). It replaces the aldosterone in their body. Adults take this medicine as pills.

Children can take these pills crushed or dissolved in water.

**Please see full [Prescribing Information here](#) and additional Important Safety Information on pages 7-8.**

### What should you do if you or your loved one have AI and don't feel well?

If you or your loved one are sick or hurt, call the doctor right away.

For most of us, the body makes more cortisol during times of stress, like when we are sick or badly injured. But in people with AI, the body can't do that. That's why they may need to take extra medicine.

At times, people with AI may need to increase their dose of medicine as their doctor prescribes. For example, if they have

- Surgery
- A high fever (101°F or higher)
- Severe infection or diarrhea, or they are vomiting and can't keep their corticosteroid pills down
- Severe injury or a serious condition (suddenly passing out)

You should not increase the dose for any other sort of stress (like having a bad day or feeling tense or sad).

**Remember to take your medicine only as your doctor instructs.**

### Selected Important Safety Information

Solu-Cortef injections may cause dips or dents in your skin, and should not be injected into your shoulder (deltoid) muscle.

Tell your doctor if you are experiencing unusual stress, as the drug dose might need to be adjusted.

Average and large doses of corticosteroids, including Solu-Cortef may cause an increase in blood pressure or swelling from water and salt retention. Increased potassium loss may occur. Tell your doctor if you have heart, kidney, adrenal, or blood pressure problems before starting the medication.

Corticosteroids, including Solu-Cortef, might cause endocrine problems such as high blood sugar. Your doctor should monitor you for these conditions if you take corticosteroids for an extended time.

## Answers to your questions about AI

### What if you or your loved one are too sick to take pills for AI?

If people with AI are too sick to take pills, or to keep them down, they must often take a shot of a medicine such as Solu-Cortef® (hydrocortisone sodium succinate for injection, USP). The shot will take the place of both kinds of pills taken for AI.

If you are too sick to take your pills, you should call your doctor or go to the nearest hospital ER right away.

You should always carry your Solu-Cortef with you.

Solu-Cortef is injected into a large muscle. The thigh is the best place for your injection to be given.

People with AI should always wear a medical alert bracelet.

Children with AI should have their guardian complete an "In Case of Emergency" form to give to the school nurse. Give the nurse a supply of Solu-Cortef to be used if needed in an emergency.

### When they feel better, should people with AI go back to taking just the pills?

People with AI should always talk to their doctor first. Typically, they can start taking their regular pills again when signs such as throwing up or diarrhea have stopped.

### Managing your AI

- Learn all you can about the illness
- Be sure you or your loved one takes AI medicine daily, as your doctor instructs
- Learn when you or your loved one is under stress, such as during illness or injury
- Schedule regular checkups
- Make sure you or your loved one wears a medical alert bracelet or other medical ID

Please see full [Prescribing Information here](#) and additional Important Safety Information on pages 7-8.

## Indication and Important Safety Information

### Indication

Solu-Cortef® (hydrocortisone sodium succinate for injection, USP) is used in the treatment of primary and secondary adrenocortical insufficiency and congenital (existing at birth) adrenal hyperplasia, both of which cause low cortisol and sometimes low aldosterone levels in the body.

### Important Safety Information

Solu-Cortef should not be used in patients with systemic fungal infections or in patients who are allergic to any of its ingredients. Severe reactions might occur.

Solu-Cortef should not be used in patients with idiopathic thrombocytopenic purpura, a condition that causes low platelets and may result in increased bleeding.

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Corticosteroids, including Solu-Cortef, might cause endocrine problems such as high blood sugar. Your doctor should monitor you for these conditions if you take corticosteroids for an extended time.

Patients who take corticosteroids, including Solu-Cortef are more likely to get infections. These infections may be mild, but can be serious and at times fatal. Corticosteroids may mask some signs and symptoms of infection or make unknown infections worse. If you develop a fever or other signs of an infection, you should call your doctor right away.

You should tell your doctor if you have visited the tropics, have diarrhea or intestinal worms, or if you have ever had or have been around someone with tuberculosis.

Tell your doctor if you are taking a corticosteroid before getting any vaccines or shots.

When taking Solu-Cortef you should avoid exposure to chicken pox or measles. If you think you were around someone with these infections, call your doctor right away.

Use of corticosteroids, including Solu-Cortef may cause eye problems such as glaucoma, infections, and cataracts.

## Important Safety Information (cont'd)

The lowest dose of Solu-Cortef should be used to treat your medical problem. When your dose can be decreased, it should be done slowly. Do not stop taking Solu-Cortef unless your doctor tells you to. You should also tell all your doctors that you are taking a corticosteroid.

Corticosteroids, including Solu-Cortef might interact with other drugs. You should tell your doctor about all the other drugs you are taking and you should not take any drug without discussing with your doctor first.

Tell your doctor if you are pregnant or plan to become pregnant. It is not known if Solu-Cortef will harm your unborn baby. Also tell your doctor if you are breastfeeding or plan to breast feed.

Solu-Cortef passes into your milk and may cause serious growth or other problems for your baby. Talk with your doctor about the best way to feed your baby if you take Solu-Cortef.

Solu-Cortef may cause fertility problems in men.

Corticosteroids, including Solu-Cortef may also cause skin problems, heart attack or failure, heart rhythm problems, tendon rupture, period irregularities, diabetes, bone loss, fractures and joint problems, depression, mood swings, and other mental health problems, brain and nervous system problems, decreased sperm count, weight gain, tiredness, muscle weakness, stomach and bowel bleeding, and growth problems in children. Call your doctor immediately if you experience any adverse signs or symptoms while taking corticosteroids including Solu-Cortef.

Please see full [Prescribing Information here](#).



To report negative side effects of prescription drugs to the Food and Drug Administration (FDA), visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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December 2023