



**Purified
Cortrophin[®]
Gel**
repository corticotropin
injection USP 80 U/mL



Cortrophin Gel Injection Guide

Multiple-dose vials

Step-by-step instructions on how to inject
Cortrophin Gel, both under the skin (subcutaneous)
and into the muscle (intramuscular)



Please see Important Safety Information throughout this brochure and full **Prescribing Information and Instructions for Use.**

Table of contents

Be sure to read this entire guide and the Instructions for Use before you begin your first injection and as needed prior to any following injections.

This guide is intended to be educational. It is not meant to be used as a substitute for specific advice or instructions from your healthcare provider.

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About Purified Cortrophin® Gel

(repository corticotropin injection USP) 80 U/mL

Once Cortrophin Gel has been prescribed, you may want to learn a little more about your medication before you begin treatment.

What is Cortrophin Gel?

Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for:

- Acute attacks or flares of multiple sclerosis.
- Short-term add-on therapy to help manage acute episodes or flares in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Treatment for flares or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.
- Treatment for people with symptoms of sarcoidosis.
- Treatment for severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina.

Cortrophin Gel is a purified, naturally sourced hormone called adrenocorticotrophic hormone, or ACTH for short. People normally produce ACTH from their pituitary gland. The ACTH in Cortrophin Gel is thought to help reduce inflammation by producing cortisol in your body and increasing other anti-inflammatory factors.

Important Safety Information

DO NOT use Cortrophin Gel if you have any of the following conditions:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Fungal infections
- Ocular herpes simplex (an eye infection)
- A recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- High blood pressure
- Allergies to pig-derived proteins
- Adrenal glands that do not make enough of the hormone cortisol (primary adrenocortical insufficiency) or
- An adrenal cortex that makes too much of the hormones cortisol and aldosterone (adrenocortical hyperfunction)



5 mL

Vial size not to scale.



1 mL

Vial size not to scale.

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 **Purified Cortrophin® Gel**
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Getting started

This step-by-step guide for administration is meant to add to the detailed discussion and training provided to you by your healthcare provider. **Do not** try to inject yourself until you have been shown how to give your injections.

Understanding how to inject

After prescribing Cortrophin Gel, your healthcare provider will give you specific advice and instructions based on your needs and condition. You will also be taught how to prepare and inject Cortrophin Gel the right way, including:

- Where and how to inject**
- How much to give**
- How often to give it**

Areas to avoid while injecting

DO NOT administer Cortrophin Gel into:

- A vein
- The mouth
- The belly button
- Areas that are red or swollen or have any irritation
- Areas that are hardened or sensitive
- Areas that have inflammation, scarring, cuts, or wounds
- The exact same site multiple times a week. Make sure you rotate the injection sites in each body area every time you inject, keeping at least 1 inch between injection sites

Call your healthcare provider if you have any problems or experience issues that keep you from continuing with your treatment.



Ask your healthcare provider which injection method you should use and the best areas for your injections.

For more detailed information about injection sites, please see pages 9 and 11.

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Collecting your supplies

Before starting, collect all the supplies you will need to use for preparing and injecting Cortrophin Gel.

You will need the following:



Vial of Cortrophin Gel.
Vial size not to scale.



Syringe



Needle for withdrawal
(20G or as prescribed
by your doctor)



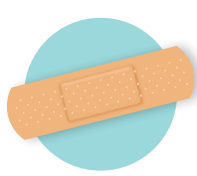
Needle for injection
(23G or as prescribed
by your doctor)



2 alcohol pads



Cotton balls or a
gauze pad



Bandage, if needed



Appropriate container
for needle disposal

Important Safety Information (continued)

Tell your doctor if you:

- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements
- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Cortrophin Gel passes into your breast milk and if it can harm your baby.

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Preparing to inject

Setting up for your injection



Before you begin your Cortrophin Gel injection, wash your hands well and dry them with a clean towel.



Be sure to double check the expiration date on your Cortrophin Gel vial.



Remember, the medicine in the vial is a solid gel and will need to be warmed to a liquid gel after you remove it from the refrigerator prior to injecting. This can be done by rolling the vial between your hands for a few minutes. You will know it is ready when the medicine is a liquid gel and not a solid gel. **DO NOT** microwave or heat the vial on the stove to warm.



Once the vial is ready, remove the plastic cap from the top of the vial and throw it away. **DO NOT** put the plastic cap back on the vial.



Then, wipe the rubber stopper on the top of the vial with a new sterile alcohol pad. Allow the alcohol to air dry. **DO NOT** wipe it off.



Take a new sterile 20G needle (or needle size as prescribed by your doctor for withdrawal) and attach it to the syringe.

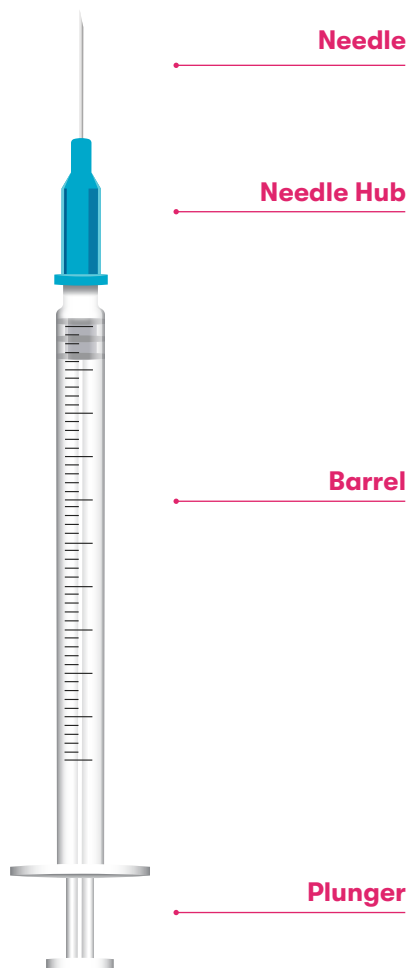
DO NOT use the vial if:

Any signs of contamination are seen, like if the gel looks cloudy or has particles in it



Vial	It has been more than:
5 mL	28 days after the vial has been opened (top seal punctured) or if the expiration date stamped on the vial has passed.
1 mL	6 months after the vial has been opened (top seal punctured) or if the expiration date stamped on the vial has passed.

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You should now be ready to load Cortrophin Gel into the syringe. Be sure to review the visual as many of these components and terms will be used in the next part of the instructions.

Before the next step, you can also use this chart to remind you how much medicine you'll need based on what your healthcare provider has prescribed.

Cortrophin Gel dose conversion chart

Units	Injection amount (mL)
120 units	1.5 mL
80 units	1 mL
40 units	0.5 mL
25 units	0.3125 mL

If you have any questions about your dose of Cortrophin Gel, ask your healthcare provider for guidance.

These are not all the possible doses of Cortrophin Gel. If you need to calculate additional doses, every 20-unit increment results in a 0.25-mL increase or decrease in injection amount. For example, 100 units = 1.25 mL.

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel?

Be sure to take Cortrophin Gel exactly as your doctor has directed. Always inject Cortrophin Gel under the skin or into the muscle. **Do not inject Cortrophin Gel directly into the vein.**

- You may be more likely to get infections. Contact your doctor at the first sign of an infection or fever.
- Your body may not produce enough natural cortisol after you stop taking Cortrophin Gel long term. This is called adrenal insufficiency. Your doctor may try to reduce your dosage gradually or prescribe a steroid medicine to protect you until the adrenal gland recovers.
- You might develop high blood pressure, retain too much salt and water, or have low blood potassium levels. As a result of this, your doctor may recommend some changes to your diet, such as eating less salt or taking certain supplements.
- Corticotropin therapy may hide symptoms of other diseases. This can make it more difficult for your doctor to make a diagnosis if something else is going on.

Preparing to inject

Loading the syringe



Remove the needle cap and insert the needle straight down through the rubber stopper at the top of the vial.



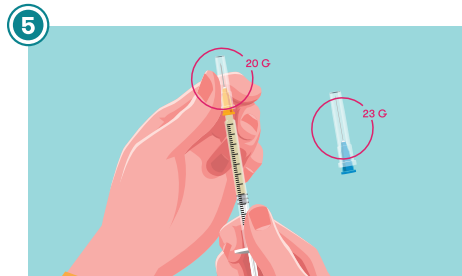
With the needle in the vial, pick up the vial and turn it upside down.



Make sure the needle is in the medicine and pull back the plunger to draw up the amount of Cortrophin Gel your healthcare provider has told you to use.



If there are any air bubbles in the syringe, tap the side of the syringe to help them rise toward the needle end. Then, slowly press the plunger until all bubbles are removed from the syringe.



Making sure no medicine is in the needle, replace the 20G needle (or the one prescribed for withdrawal) with the 23G needle (or the one prescribed for injection). Use caution when replacing the needle. If you withdrew your medicine with the needle you will use for injection, you can proceed to the following section.

✗ DO NOT use the 20G needle for injecting

You are now ready to inject.

Be sure to check that you still have the right amount of medicine in the syringe for injection before removing the needle from the vial. Once confirmed, you can return the Cortrophin Gel vial to the refrigerator.

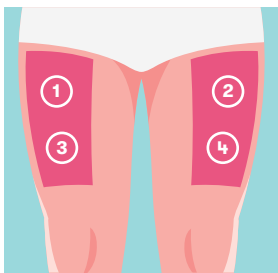
Injecting under the skin

! These instructions are for injections under the skin (subcutaneous) only

Locating where to inject

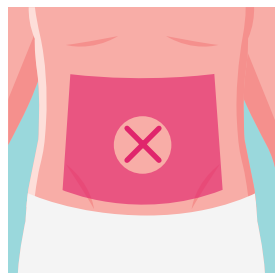
Before you administer treatment to yourself or someone else, it's important you decide where your injection site will be. Ask your healthcare provider which injection areas are best for you.

Appropriate areas for subcutaneous (under the skin) injection



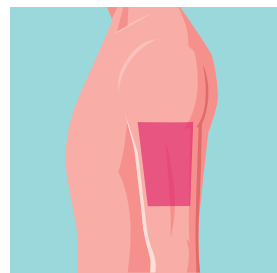
Upper thigh:

The injection area is in the center of your thigh to the outer side of the leg.



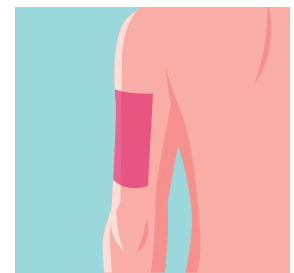
Abdomen:

The injection area is under your lower ribs in any area that has enough tissue to pinch. **DO NOT** inject into your belly button.



Side of upper arm:

The injection area is on the outer side of the upper arm between the bottom of the shoulder bone and the elbow in any area that has enough tissue to pinch.

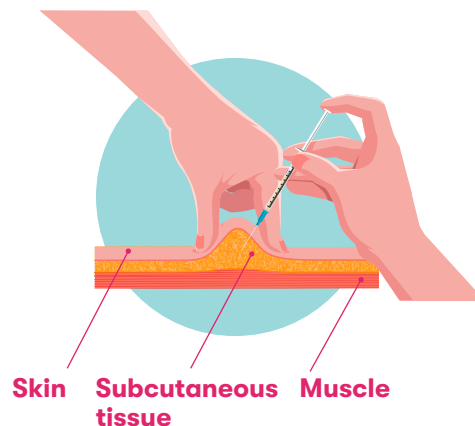


Back of upper arm:

The injection area is on the back side of the upper arm between the bottom of the shoulder bone and the elbow in any area that has enough tissue to pinch.



You may inject into the same area multiple times a week, but make sure you rotate the injection sites in that area each time, keeping at least 1 inch between sites.



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Injecting under the skin

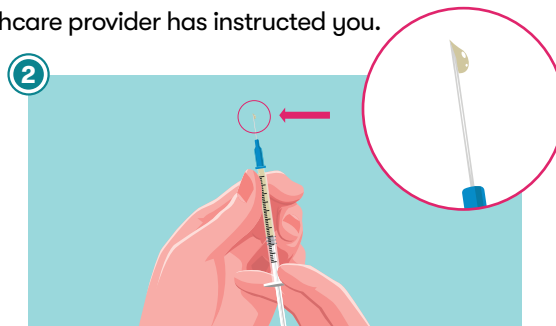
Giving the injection

It's important to give the injection the way your healthcare provider has instructed you.



Disinfect the injection area

Prepare the skin where you are going to give the injection by wiping it with a new sterile alcohol pad. Allow it to air dry.



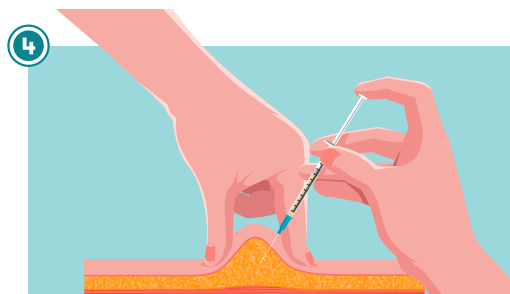
Hold the syringe with the needle up and slowly push the plunger until a small droplet forms at the needle tip

Prime the needle for injecting by slowly pushing the plunger until a small droplet of medicine forms at the tip of the 23G needle (or needle size prescribed for injection).



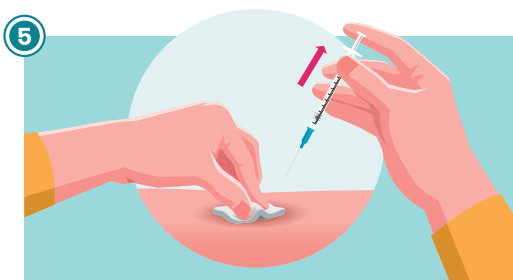
Pinch the skin around the injection site

DO NOT touch the site where you plan to inject Cortrophin Gel.



Insert the needle at a 45-degree angle through the skin using a quick motion

Stop pinching the skin and then push down on the plunger until all the medicine is emptied from the syringe.



Remove the needle

Pull the needle out, being careful not to bend or twist it. Once the needle is removed, there may be a little bleeding at the injection site. You can press a cotton ball or gauze pad over the injection site (do not rub). You may cover the injection site with a bandage, if needed.



Keep track of your injections by downloading the Cortrophin Gel Injection Calendar at Cortrophin.com.

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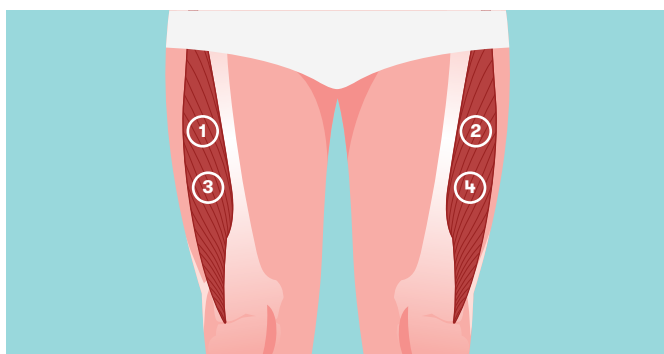
Injecting into the muscle

! These instructions are for injections into the muscle (intramuscular) only

Locating where to inject

Before you administer treatment to yourself or someone else, it's important to decide where your injection site will be. In some people, certain muscles may not be suitable for injections, so ask your healthcare provider which injection areas are best for you.

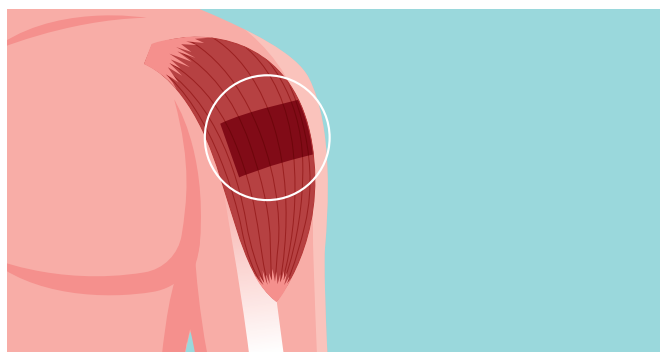
Appropriate areas for intramuscular (into the muscle) injection



Upper-outer thigh muscle:

The injection area is into the middle third of the muscle that runs along the upper-outer edge of the thigh bone.

To find the middle third, place the fingertips of one hand on your knee with your palm resting on your thigh. Place the fingertips of your free hand behind the palm of the first hand. The outer area under your second hand is the area to inject.

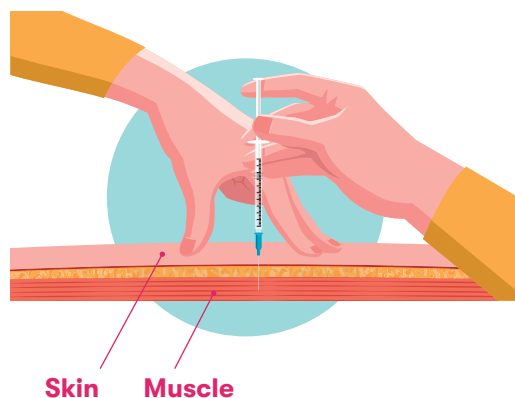


Upper-arm muscle:

The injection area is 3 fingertip widths below the shoulder bone on the outer part of the upper arm.



You may inject into the same area multiple times a week, but make sure you rotate the injection sites in that area each time, keeping at least 1 inch between sites.



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Injecting into the muscle

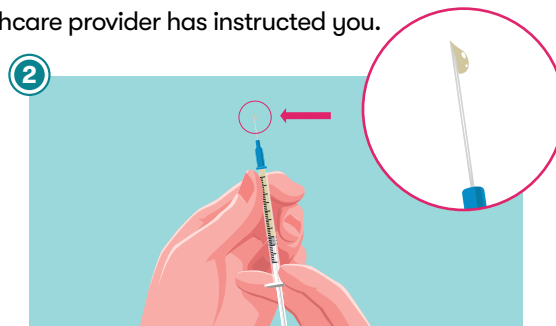
Giving the injection

It's important to give the injection the way your healthcare provider has instructed you.



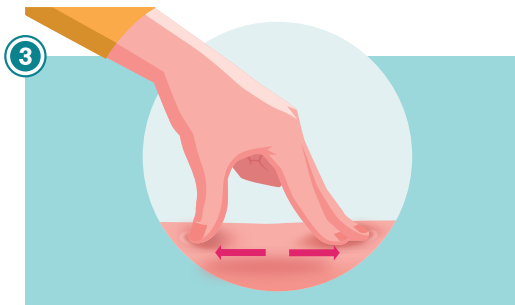
Disinfect the injection area

Prepare the skin where you are going to give the injection by wiping it with a new sterile alcohol pad. Allow it to air dry.

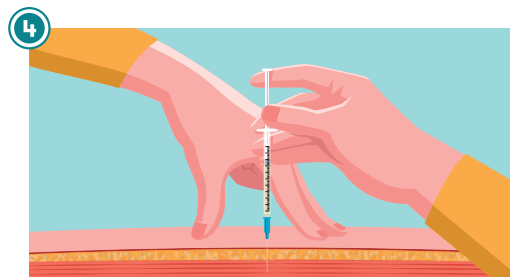


Hold the syringe with the needle up and slowly push the plunger until a small droplet forms at the needle tip

Prime the needle for injecting by slowly pushing the plunger until a small droplet of medicine forms at the tip of the 23G needle (or needle size prescribed for injection).

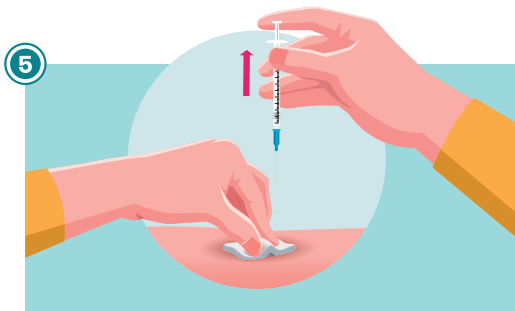


Stretch and hold the skin around the injection site



Insert the needle at a 90-degree angle through the skin using a quick motion

Stop stretching the skin and then push down on the plunger until all the medicine is emptied from the syringe.



Remove the needle

Pull the needle out, being careful not to bend or twist it. Once the needle is removed, there may be a little bleeding at the injection site. You can press a cotton ball or gauze pad over the injection site (do not rub). You may cover the injection site with a bandage, if needed.



Keep track of your injections by downloading the Cortrophin Gel Injection Calendar at Cortrophin.com.

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Throwing away (disposing of) used supplies after injection

Make sure you follow state and local laws regarding proper disposal of used medical supplies. Your healthcare provider can help provide more information about this process.

Put any used needles and syringes in an FDA-cleared sharps container right away after completing treatment.

DO NOT:

- Throw away (dispose of) your used needles and syringes in your household trash
- Reuse or recycle used supplies
- Store used supplies in a clear plastic or glass container

If you do not have a sharps container, use a container made of heavy plastic, like a detergent bottle, that:

- Has a tight-fitted lid
- Is puncture- and leak-resistant
- Is properly labeled to warn of hazardous waste inside



When to throw away Cortrophin Gel vials

Vial	When to throw away (discard)
5 mL	28 days after the vial has been opened (top seal punctured) or by the expiration date stamped on the vial, whichever occurs first.
1 mL	6 months after the vial has been opened (top seal punctured) or by the expiration date stamped on the vial, whichever occurs first.

Reminder:



Write the revised “discard by” date in the space provided on the carton.



Once your container is full, follow the appropriate disposal instructions for your state by:

- Speaking with your doctor, nurse, or pharmacist
- Visiting the FDA’s website at [FDA.gov/SafeSharpsDisposal](https://www.fda.gov/SafeSharpsDisposal)

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Support program



Support that's designed to help you throughout the treatment process

Cortrophin In Your Corner is a dedicated program designed to support you and help you access treatment. Once you are prescribed Cortrophin Gel, the Cortrophin In Your Corner program* can provide you with support and educational information throughout your treatment.

Our team of experts is here to help you:

- Obtain information on insurance coverage and financial support including copay assistance
- Coordinate shipments with the specialty pharmacy supplying your medication (if applicable)
- Get access to useful resources and answers to questions you may have
- A dedicated Nurse Access Specialist[†] may help you navigate the treatment process and facilitate additional injection training for you
- A support center is available to answer your questions and provide educational information

***Not all patients will be eligible for all services offered by Cortrophin In Your Corner.**

[†]Nurse Access Specialists do not give medical advice and will direct you to your healthcare professional for any treatment-related questions.



Questions? Call us at 1-888-CIYC-NOW (1-888-249-2669)

Or for more information about Cortrophin In Your Corner, visit [Cortrophin.com/Support](https://www.cortrophin.com/Support)

Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel? (continued)

- Taking Cortrophin Gel can make you feel irritable or depressed. You may also have mood swings or trouble sleeping.
- You might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage.
- You may develop allergies to Cortrophin Gel. These allergies may be severe. Signs of an allergic reaction include dizziness, nausea and vomiting, skin reactions (rash or itching), swelling of the face, tongue, lips or throat, and trouble breathing.
- The effects of Cortrophin Gel may be intensified if you have an underactive thyroid or cirrhosis of the liver.

Side effects of Cortrophin Gel include fluid or salt retention; weight gain; muscle weakness; osteoporosis, stomach ulcers with possible bleeding; injection site reactions; impaired wound healing; high blood pressure; convulsions; headache; development of Cushingoid state (a hormonal condition often characterized by facial puffiness and weight gain); suppression of growth in children; and allergic reactions that may be severe.

These are not all of the possible side effects of Cortrophin Gel. Call your doctor or pharmacist for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Use & Safety Information

Indications

What is Purified Cortrophin Gel?

Purified Cortrophin Gel is a prescription medicine that is injected under the skin or into the muscle. It is used for:

- Short-term add-on therapy to help manage acute episodes or flares in rheumatoid arthritis, including juvenile rheumatoid arthritis; psoriatic arthritis; ankylosing spondylitis; and acute gouty arthritis.
- Treatment for flares or as maintenance therapy in select cases of systemic lupus erythematosus and systemic dermatomyositis (polymyositis).
- Treatment for severe skin reactions (Stevens-Johnson syndrome) and severe psoriasis.
- Treatment for atopic dermatitis (eczema) and serum sickness.
- Treatment for severe acute and chronic allergic and inflammatory conditions affecting different parts of the eye. This can include the front part of the eye such as the cornea and iris, or the back part of the eye such as the optic nerve and retina.
- Treatment for people with symptoms of sarcoidosis.
- Reduction of protein in the urine of people with nephrotic syndrome of the idiopathic type (unknown origin) without uremia (accumulation of urea in the blood due to malfunctioning kidneys) or due to lupus.
- Acute attacks or flares of multiple sclerosis.

Important Safety Information

DO NOT use Cortrophin Gel if you have any of the following conditions:

- A skin condition called scleroderma
- Bone density loss or osteoporosis
- Fungal infections
- Ocular herpes simplex (an eye infection)
- A recent surgery
- Stomach ulcers or a history of stomach ulcers
- Heart failure
- High blood pressure
- Allergies to pig-derived proteins
- Adrenal glands that do not make enough of the hormone cortisol (primary adrenocortical insufficiency) or
- An adrenal cortex that makes too much of the hormones cortisol and aldosterone (adrenocortical hyperfunction)

Tell your doctor if you:

- Have or have had any other health problems
- Are taking any prescription or over-the-counter medicines, including aspirin, vitamins, and herbal or dietary supplements
- Have any allergies
- Are about to receive any vaccine
- Are pregnant or plan to become pregnant. Cortrophin Gel may harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Cortrophin Gel passes into your breast milk and if it can harm your baby.

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Important Safety Information (continued)

What important information do I need to know about Cortrophin Gel?

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- You might develop certain eye conditions, such as cataracts, glaucoma, or optic nerve damage.

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Scan this code to watch a video about using Cortrophin Gel.