

[Home](#) → [Drugs, Herbs and Supplements](#) → Adalimumab Injection

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## Adalimumab Injection

pronounced as (a dal aye' mu mab)

### IMPORTANT WARNING:

Using adalimumab injection may decrease your ability to fight infection and increase the chance that you will develop a serious infection, including severe fungal, bacterial, and viral infection that may spread through the body. These infections may need to be treated in a hospital and may cause death. Tell your doctor if you often get any type of infection or if you have or think you may have any type of infection now. This includes minor infections (such as open cuts or sores), infections that come and go (such as cold sores) or chronic infections that do not go away. Also tell your doctor if you have or have ever had any condition that affects your immune system or if you live or have ever lived in areas such as the Ohio or Mississippi river valleys where severe fungal infections are more common. Ask your doctor if you don't know if these infections are more common in your area. Tell your doctor if you are taking medications that decrease the activity of the immune system such as the following: abatacept (Orencia), anakinra (Kineret), certolizumab (Cimzia), etanercept (Enbrel), golimumab (Simponi), infliximab (Remicade), methotrexate (Otrexup, Rasuvo, Trexall), rituximab (Rituxan), or steroids such as dexamethasone, methylprednisolone (Medrol), prednisone (Rayos), or prednisolone (Prelone).

Your doctor will monitor you for signs of infection during and after your treatment. If you have any of the following symptoms before you begin your treatment or if you experience any of the following symptoms during or shortly after your treatment, call your doctor immediately: weakness; sweating; sore throat; cough; coughing up bloody mucus; fever; weight loss; extreme tiredness; diarrhea; stomach pain; warm, red, or painful skin; painful, difficult, or frequent urination; or other signs of infection.

You may already be infected with tuberculosis (TB; a serious lung infection) or hepatitis B (a virus that affects the liver) but not have any symptoms of the disease. In this case, adalimumab injection may increase the risk that your infection will become more serious and you will develop symptoms. Your doctor will perform a skin test to see if you have an inactive TB infection and may order a blood test to see if you have an inactive hepatitis B infection. If necessary, your doctor may give you medication to treat this infection before you begin your treatment with adalimumab. Tell your doctor if you have or have ever had TB, if you have lived in or visited a country where TB is common, or if you have been around someone who has or has ever had TB. If you have any of the following symptoms of TB, or if you develop any of these symptoms during your treatment, call your doctor

immediately: cough, weight loss, loss of muscle tone, fever, or night sweats. Also call your doctor immediately if you have any of these symptoms of hepatitis B or if you develop any of these symptoms during or after your treatment: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea or vomiting, muscle aches, dark urine, clay-colored bowel movements, fever, chills, stomach pain, or rash.

Some children, teenagers, and young adults who received adalimumab injection or similar medications developed severe or life-threatening cancers including lymphoma (cancer that begins in the cells that fight infection). Some teenage and young adult males who took adalimumab or similar medications developed hepatosplenic T-cell lymphoma (HSTCL), a very serious form of cancer that often causes death within a short period of time. Most of the people who developed HSTCL were being treated for Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) or ulcerative colitis (a condition which causes swelling and sores in the lining of the colon [large intestine] and rectum) with adalimumab or a similar medication along with another medication called azathioprine (Imuran) or 6-mercaptopurine (Purinethol). Tell your child's doctor if your child has ever had any type of cancer. If your child develops any of these symptoms during his or her treatment, call his or her doctor immediately: stomach pain; fever; unexplained weight loss; swollen glands in the neck, underarms, or groin; or easy bruising or bleeding. Talk to your child's doctor about the risks of giving adalimumab injection to your child.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with adalimumab injection and each time you receive the medication. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using adalimumab injection.

## Why is this medication prescribed?

**Adalimumab injection is used alone or with other medications to relieve the symptoms of certain autoimmune disorders (conditions in which the immune system attacks healthy parts of the body and causes pain, swelling, and damage) including the following:**

- rheumatoid arthritis (a condition in which the body attacks its own joints, causing pain, swelling, and loss of function) in adults,
- juvenile idiopathic arthritis (JIA; a condition that affects children in which the body attacks its own joints, causing pain, swelling, loss of function, and delays in growth and development) in children 2 years of age and older,
- Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) that has not improved when treated with other medications in adults and children 6 years of age and older,

- ulcerative colitis (a condition which causes swelling and sores in the lining of the colon [large intestine] and rectum) when other medications and treatments did not help or could not be tolerated in adults and children 5 years of age and older,
- ankylosing spondylitis (a condition in which the body attacks the joints of the spine and other areas causing pain and joint damage) in adults,
- psoriatic arthritis (a condition that causes joint pain and swelling and scales on the skin) in adults,
- hidradenitis suppurativa (a skin disease that causes pimple-like bumps in the armpits, groin, and anal area) in adults and children 12 years of age and older,
- uveitis (swelling and inflammation of different areas of the eye) in adults and children 2 years of age and older,
- chronic plaque psoriasis (a skin disease in which red, scaly patches form on some areas of the body) in adults.

Adalimumab injection is in a class of medications called tumor necrosis factor (TNF) inhibitors. It works by blocking the action of TNF, a substance in the body that causes inflammation.

## How should this medicine be used?

Adalimumab injection comes as a solution (liquid) to inject subcutaneously (under the skin). Your doctor will tell you how often to use adalimumab based on your condition and age. To help you remember to inject adalimumab injection, mark the days you are scheduled to inject it on your calendar. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use adalimumab injection exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

You will receive your first dose of adalimumab injection in your doctor's office. After that, you can inject adalimumab injection yourself or have a friend or relative perform the injections. Before you use adalimumab injection yourself the first time, read the written instructions that come with it. Ask your doctor or pharmacist to show you or the person who will be injecting the medication how to inject it.

Adalimumab injection comes in prefilled syringes and dosing pens. Use each syringe or pen only once and inject all the solution in the syringe or pen. Even if there is still some solution left in the syringe or pen after you inject, do not inject again. Dispose of used syringes and pens in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

If you are using a prefilled syringe or a dosing pen that has been refrigerated, place the syringe or pen on a flat surface without removing the needle cap and allow it warm to room temperature for 15 to 30 minutes before you are ready to inject the medication. Do not try to warm the medication by heating it in a microwave, placing it in hot water, or through any other method.

Be careful not to drop or crush the prefilled syringes or dosing pens. These devices are made of glass or contain glass and may break if they are dropped.

You can inject adalimumab injection anywhere on the front of your thighs or stomach except your navel and the area 2 inches (5 centimeters) around it. To reduce the chances of soreness or redness, use a

different site for each injection. Give each injection at least 1 inch (2.5 centimeters) away from a spot that you have already used. Keep a list of the places where you have given injections so that you will not inject in these places again. Do not inject into an area where the skin is tender, bruised, red, or hard or where you have scars or stretch marks.

Always look at adalimumab injection solution before injecting it. Check that the expiration date has not passed, that the syringe or dosing pen contains the correct amount of liquid, and that the liquid is clear and colorless. Do not use a syringe or dosing pen if it is expired, if it does not contain the correct amount of liquid, or if the liquid is cloudy or contains flakes.

Adalimumab injection may help control your condition but will not cure it. Continue to use adalimumab injection even if you feel well. Do not stop using adalimumab injection without talking to your doctor.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before using adalimumab injection,

- tell your doctor and pharmacist if you are allergic to adalimumab injection, any other medications, or any of the ingredients in adalimumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients. If you will be using the prefilled syringe, also tell your doctor if you or the person who will be helping you inject adalimumab injection are allergic to latex or rubber.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: cyclosporine (Gengraf, Neoral, Sandimmune), theophylline (Elixophyllin, Theo 24, Theochron), or warfarin (Coumadin, Jantoven). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- in addition to the conditions mentioned in the IMPORTANT WARNING section, tell your doctor if you have or have ever had numbness or tingling in any part of your body, any disease that affects your nervous system, such as multiple sclerosis (a disease in which the nerves do not function properly causing weakness, numbness, loss of muscle coordination and problems with vision, speech, and bladder control), Guillain-Barré syndrome (weakness, tingling, and possible paralysis due to sudden nerve damage), or optic neuritis (inflammation of the nerve that sends messages from the eye to the brain); any type of cancer, diabetes, heart failure, or heart disease. If you have psoriasis, tell your doctor if you have been treated with light therapy.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using adalimumab injection, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using adalimumab injection.
- do not have any vaccinations without talking to your doctor. If your child will be receiving adalimumab injection, be sure that your child has received all the shots that are required for children of his or her age before he or she begins treatment with adalimumab injection.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Inject the missed dose as soon as you remember it. Then inject the next dose on your regularly scheduled day. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not use a double dose to make up for a missed one.

## What side effects can this medication cause?

**Adalimumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- redness, itching, bruising, pain, or swelling in the place you injected adalimumab injection
- nausea
- headache
- back pain

**Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately or get emergency care:**

- numbness or tingling
- problems with vision
- weakness in legs
- chest pain
- shortness of breath
- rash, especially a rash on the cheeks or arms that is sensitive to sunlight
- new joint pain
- hives
- itching
- swelling of the face, feet, ankles, or lower legs
- difficulty breathing or swallowing
- fever, sore throat, chills, and other signs of infection
- unusual bruising or bleeding
- pale skin
- dizziness
- red, scaly patches or pus-filled bumps on the skin

Adults who receive adalimumab injection may be more likely to develop skin cancer, lymphoma, and other types of cancer than people who do not receive adalimumab injection. Talk to your doctor about the

risks of receiving this medication.

Adalimumab injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it in the refrigerator and protect it from light. Adalimumab injection may also be stored at room temperature (up to 77°F [25°C]) for up to 14 days and protected from light. If adalimumab injection is stored at room temperature for more than 14 days and it is not used, it must be disposed. Do not freeze it. Dispose of any medication that has been frozen.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before, during, and after your treatment to check your body's response to adalimumab.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary

supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Humira<sup>®</sup> Injection

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