

### **Drugs and Supplements**

# Adalimumab (Subcutaneous Route)

## **Description and Brand Names**

Drug information provided by: IBM Micromedex

### **US Brand Name**

## ABRILADA Descriptions

Amjevita

Cyltezo

Hadlima

Hulio

Humira

Hyrimoz

Adalimumab injection is used to treat the symptoms and prevent the progression of active rheumatoid arthritis and ankylosing spondylitis. It is used in children 2 years of age and older for juvenile idiopathic arthritis. This medicine is also used to treat psoriatic arthritis, which is a type of arthritis that causes pain and swelling in the joints along with patches of scaly skin on some areas of the body. Psoriatic arthritis usually occurs with a skin condition called psoriasis. Adalimumab may be used alone or in combination with medicines (eg, methotrexate or DMARDs).

Adalimumab injection is also used to treat the symptoms of active Crohn's disease in patients who have not been helped by other medicines, such as infliximab. It is also used to treat moderate to severe ulcerative colitis in patients who have been treated with other medicines (eg, azathioprine, corticosteroids, or 6-mercaptopurine) that did not work well.

Adalimumab injection may also be used to treat chronic plaque psoriasis, which is a skin disease with red patches and white scales that do not go away. It is also used to treat moderate to severe hidradenitis suppurativa, a chronic skin disease that has small, painful lumps under the skin in adults and children 12 years of age and older. This medicine is also used to treat non-infectious intermediate, posterior and panuveitis in adults and children 2 years of age and older.

This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

Solution

## **Before Using**

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

### **Allergies**

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

### **Pediatric**

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of adalimumab injection for the treatment of juvenile idiopathic arthritis and non-infectious uveitis in children 2 years of age and older or for the treatment of hidradenitis suppurativa in children 12 years of age and older. However, safety and efficacy have not been established in children younger than 2 years of age for juvenile idiopathic arthritis and non-infectious uveitis, in children younger than 6 years of age for Crohn's disease, in children younger than 12 years of age for hidradenitis suppurativa, and in children for other conditions.

### **Geriatric**

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of adalimumab injection in the elderly. However, this medicine may cause serious infections and cancer more often in the elderly, which may require caution in patients receiving adalimumab injection.

### **Breastfeeding**

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

### **Drug Interactions**

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

#### Abatacept

- Adenovirus Vaccine
- Anakinra
- Bacillus of Calmette and Guerin Vaccine, Live
- · Cholera Vaccine, Live
- Dengue Tetravalent Vaccine, Live
- Infliximab
- · Influenza Virus Vaccine, Live
- Measles Virus Vaccine, Live
- · Mumps Virus Vaccine, Live
- Poliovirus Vaccine, Live
- Rilonacept
- Rotavirus Vaccine, Live
- Rubella Virus Vaccine, Live
- Smallpox Vaccine
- Tofacitinib
- Typhoid Vaccine
- Varicella Virus Vaccine, Live
- Yellow Fever Vaccine
- · Zoster Vaccine, Live

#### Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

### **Other Medical Problems**

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Blood problems (eg, aplastic anemia, pancytopenia, thrombocytopenia), history of or
- Congestive heart failure or
- Guillain-Barré syndrome, history of or
- Infections (fungal, bacterial), history of or
- Leukopenia (low number of white blood cells) or
- · Multiple sclerosis or
- Optic neuritis (eye problem) or

- Psoriasis (skin disease)—Use with caution. May make these conditions worse.
- Cancer, active or history of or
- Chronic obstructive pulmonary disease (COPD) or
- Granulomatosis polyangiitis—Use with caution. May increase the chance of getting new cancers.
- Diabetes or
- Hepatitis B, history of or
- · Opportunistic infections, history of or
- Tuberculosis, history of—May increase chance for more side effects.
- Infection, active—Should not be used in patients with this condition.
- Tuberculosis, active—Should be treated first before receiving this medicine.

## **Proper Use**

This medicine is given as a shot under your skin. Adalimumab may sometimes be given at home to patients who do not need to be in the hospital or clinic. If you are using this medicine at home, your doctor or nurse will teach you how to prepare and inject the medicine. Be sure that you understand how to use the medicine.

This medicine comes with a Medication Guide and a Patient Instructions for Use leaflet. Read and follow the instructions carefully. Ask your doctor if you have any questions.

If you use this medicine at home, you will be shown the body areas where this shot can be given. Use a different body area each time you give yourself or your child a shot. Keep track of where you give each shot to make sure you rotate body areas. This will help prevent skin problems.

Do not inject into skin areas that are red, bruised, tender, or hard. If you have psoriasis, do not inject into a raised, thick, red, or scaly skin patch or into skin lesions.

This medicine is available in 2 forms. You may use a pen or a prefilled syringe.

To use thepen or syringe:

- First, gather the items you will need on a clean, flat surface using a cloth or towel in a welllighted area.
- Wash your hands with soap and water before and after using this medicine.
- Remove the carton with the syringe or pen from the refrigerator and place it on the cloth.
- Allow 15 to 30 minutes for the syringe or pen to warm up to room temperature. Do not warm this medicine in any other way.
- Do not remove the needle cover on the prefilled syringe or pen while allowing the medicine to reach room temperature. Remove these right away before use.

- Check the liquid in the syringe or pen using the viewing window. It should be clear and colorless. If it is cloudy, discolored, or has particles floating in it, do not use the syringe or pen.
- Check that the amount of liquid in the pen is the same or close to the fill line seen on the window. The fill line shows a full dose of the medicine. If the pen does not have the full amount of liquid, do not use it. Call your pharmacist.
- If the liquid is clear, place it on a clean, flat surface. Do not shake the medicine.
- Check the expiration date on the prefilled syringe or pen, and make sure the date has not passed. Do not use the medicine if the date has passed.
- Choose an injection site on your body (eg, thigh or stomach area). Clean the injection site with a fresh alcohol wipe and let it dry.
- Remove the cap or needle cover when you are ready to inject. Inject the full amount of medicine within a few minutes after the cap or cover has been removed.
- You might have a small amount of blood or liquid at the injection site. Press and hold a dry, clean cotton ball on the injection site for 10 seconds, but do not rub it.

### **Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For injection dosage forms (pen or prefilled syringe):
  - For Crohn's disease:
    - Adults and children 6 years of age and older weighing 40 kilograms (kg) or more—At first (week 0), 160 milligrams (mg) injected under the skin in divided doses. This may be given as four shots in 1 day or as two shots per day for 2 days. Then 2 weeks later, a dose of 80 mg is given. A maintenance dose of 40 mg is given at week 4 and every other week thereafter.
    - Children 6 years of age and older weighing 17 kg and less than 40 kg—At first (week 0), 80 mg injected under the skin in divided doses. This may be given as two shots in 1 day. Then 2 weeks later, a dose of 40 mg is given. A maintenance dose of 20 mg is given at week 4 and every other week thereafter.
    - Children younger than 6 years of age—Use and dose must be determined by your doctor.
  - For hidradenitis suppurativa:
    - Adults—At first (week 0), 160 milligrams (mg) injected under the skin in divided doses. This may be given as four shots in 1 day or as two shots per day for 2 days. Then 2 weeks later, a dose of 80 mg is given. A maintenance dose of 40 mg every week or 80 mg every other week is given starting at week 4.

- Children 12 years of age and older weighing 60 kilograms (kg) or more—Dose is based on body weight and must be given by your doctor. At first (week 0), 160 mg injected under the skin in divided doses. This may be given as four shots in 1 day or as two shots per day for 2 days. Then 2 weeks later, a dose of 80 mg is given. A maintenance dose of 40 mg every week or 80 mg every other week is given starting at week 4.
- Children 12 years of age and older weighing 30 kg to 59 kg—Dose is based on body weight and must be given by your doctor. At first (Day 1), 80 mg injected under the skin, then 40 mg on Day 8. A maintenance dose of 40 mg is given every other week.
- Children younger than 12 years of age or weighing less than 30 kg—Use and dose must be determined by your doctor.

#### For juvenile idiopathic arthritis:

- Children 2 to 17 years of age weighing 30 kilograms (kg) or more—40 milligrams (mg) injected under the skin every other week.
- Children 2 to 17 years of age weighing 15 to less than 30 kg—20 mg injected under the skin every other week.
- Children 2 to 17 years of age weighing 10 to less than 15 kg—10 mg injected under the skin every other week.
- Children younger than 2 years of age or weighing less than 10 kg—Use and dose must be determined by your doctor.

### For plaque psoriasis:

- Adults—At first, 80 milligrams (mg) injected under the skin, then 40 mg 1 week after the initial dose and every other week thereafter.
- Children—Use and dose must be determined by your doctor.
- For psoriatic arthritis, rheumatoid arthritis, or ankylosing spondylitis:
  - Adults—40 milligrams (mg) injected under the skin every other week. Your doctor may adjust your dose as needed. Some patients with rheumatoid arthritis who are not taking methotrexate may use 40 mg every week or 80 mg every other week.
  - Children—Use and dose must be determined by your doctor.

#### For ulcerative colitis:

- Adults—At first (week 0), 160 milligrams (mg) injected under the skin in divided doses. This may be given as four shots in 1 day or as two shots per day for 2 days. Then 2 weeks later, a dose of 80 mg is given. A maintenance dose of 40 mg is given at week 4 and every other week thereafter.
- Children—Use and dose must be determined by your doctor.

#### For uveitis:

- Adults—At first, 80 milligrams (mg) injected under the skin, then 40 mg 1 week after the initial dose and every other week thereafter.
- Children 2 to 17 years of age weighing 30 kilograms (kg) or more—40 milligrams (mg) injected under the skin every other week.

- Children 2 to 17 years of age weighing 15 to less than 30 kg—20 mg injected under the skin every other week.
- Children 2 to 17 years of age weighing 10 to less than 15 kg—10 mg injected under the skin every other week.
- Children younger than 2 years of age or weighing less than 10 kg—Use and dose must be determined by your doctor.

### **Missed Dose**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

### **Storage**

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store in the refrigerator. Do not freeze.

Keep the medicine in its original carton to protect from light. Do not use it if it has been frozen or thawed. If traveling, you may store this medicine at room temperature for up to 14 days. Throw away any unused medicine after 14 days. Do not store this medicine in extreme heat or cold temperatures.

Throw away used syringes or pens in a hard, closed container that where the needles cannot poke through. Keep this container away from children and pets.

### **Precautions**

If you will be using this medicine for a long time, it is very important that your doctor check your or your child's progress at regular visits. This will allow your doctor to see if this medicine is working properly and to decide whether you should continue to use it. Blood and urine tests may be needed to check for unwanted effects.

You or your child will need to have a skin test for tuberculosis before using this medicine. Tell your doctor if you or anyone in your home has ever had a positive reaction to a tuberculosis skin test.

Adalimumab can temporarily lower the number of white blood cells in your blood, which may increase the chance of getting an infection. It can also lower the number of platelets, which are necessary for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

• If you can, avoid people with infections. Check with your doctor right away if you or your child think you are getting an infection or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

- Check with your doctor right away if you or your child notice any unusual bleeding or bruising, black, tarry stools, blood in the urine or stools, or pinpoint red spots on your skin.
- Be careful when using a regular toothbrush, dental floss, or toothpick. Your medical doctor, dentist, or nurse may recommend other ways to clean your teeth and gums. Check with your medical doctor before having any dental work done.
- Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters.
- · Avoid contact sports or other situations where bruising or injury could occur.

Do not take other medicines unless they have been discussed with your doctor. Using abatacept (Orencia®) or anakinra (Kineret®) together with this medicine may increase your risk of having serious side effects.

This medicine may cause other unwanted effects that may not occur until months or years after this medicine is used. A small number of people (including children and teenagers) who have used this type of medicine have developed certain types of cancer (eg, leukemia). Some patients also developed a rare type of cancer called lymphoma. Talk with your doctor if you or your child have unusual bleeding, bruising, or weakness, swollen lymph nodes in the neck, underarms, or groin, or unexplained weight loss. Also, check with your doctor right away if your or your child's skin has red, scaly patches, or raised bumps that are filled with pus.

Adalimumab may cause serious allergic reactions, including anaphylaxis, which can be life-threatening and requires immediate medical attention. Check with your doctor right away if you or your child have a rash, itching, swelling of the face, throat, legs, or feet, trouble breathing, or chest pain after you receive the medicine.

Check with your doctor right away if you or your child has swelling of the face, fingers, feet, or lower legs, or sudden weight gain. These may be signs of a heart condition called congestive heart failure (CHF).

Some people who have used this medicine developed lupus-like symptoms during treatment and got better after the medicine was stopped. Check with your doctor right away if you or your child start having chest pains, joint pain, or a rash on the cheeks or arms that is sensitive to the sun.

Do not have any live vaccines (immunizations) while you or your child are being treated with adalimumab. Your child's vaccines need to be current before using adalimumab. Be sure to ask your child's doctor if you have any questions about this.

The needle cover of some prefilled syringes and pens contain dry natural rubber (a derivative of latex), which may cause allergic reactions in people who are sensitive to latex. Tell your doctor if you or your child have a latex allergy before using this medicine.

Serious skin reactions can occur during treatment with this medicine. Check with your doctor right away if you or your child has blistering, peeling, or loosening of the skin, red skin lesions, severe acne or skin rash, sores or ulcers on the skin, or fever or chills while using this medicine.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

## **Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

#### More common

- · Body aches or pain
- cough
- · ear congestion
- gas with stomach pain
- hoarseness
- lightheadedness
- loss of voice
- · lower back or side pain
- · muscle aches and pains
- pain or tenderness around the eyes or cheekbones
- · rapid and sometimes shallow breathing
- shivering
- stomach fullness
- · stuffy nose
- sunken eyes
- thirst
- · trouble sleeping
- warmth on the skin
- · wrinkled skin

#### Less common

- Abnormal vaginal bleeding or discharge
- · agitation
- · arm, back, or jaw pain
- · black, tarry stools
- bleeding from the gums or nose

- blindness
- · bloating or swelling of the face, arms, hands, lower legs, or feet
- blood in the stool or change in bowel habits
- bloody or cloudy urine
- blurred vision
- broken bones
- · change in size, shape, or color of an existing mole
- change in skin color
- chest pain, tightness, or heaviness
- chills
- clear or bloody discharge from the nipple
- cold hands and feet
- confusion
- constipation
- cough
- · coughing or spitting up blood
- · decreased urination
- decreased vision
- depression
- difficulty with breathing
- difficulty, burning, or painful urination
- dimpling of the breast skin
- dizziness
- drowsiness
- · eye pain
- fainting
- · fast, slow, or irregular heartbeat
- fever
- forgetfulness
- frequent urge to urinate
- · general feeling of illness
- hair loss
- headache
- hives, itching, skin rash
- increased thirst

- inverted nipple
- irregular breathing
- irregular pulse
- irritability
- · light colored stools
- loss of appetite
- lump in the breast or under your arm
- lump or swelling in the stomach
- mole that leaks fluid or bleeds
- muscle cramps or spasms
- nausea
- · new mole
- night sweats
- no blood pressure or pulse
- noisy breathing
- numbness or tingling in your arms, legs, or face
- pain, redness, or swelling in the arms or legs without any injury present
- pale skin
- persistent non-healing sore on your skin
- pink growth
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- · raised, firm, or bright red patch
- redness or swelling of the breast
- seeing or hearing things that are not there
- seizures
- sharp back pain just below your ribs
- shiny bump on your skin
- · slurred speech or problems with swallowing
- sneezing
- sore on the skin of the breast that does not heal
- sore throat
- · sores, ulcers, or white spots on the lips or mouth
- spitting up blood
- stiff neck
- · stomach pain

- stopping of the heart
- · sudden high fever or low grade fever for months
- sweating
- swelling of the face, fingers, feet, or lower legs
- swollen glands
- swollen neck veins
- tiredness
- · trouble breathing
- trouble thinking
- unconsciousness
- · unexplained bruising or bleeding
- unpleasant breath odor
- unusual tiredness or weakness
- unusual weight gain or loss
- visual disturbances
- vomiting
- vomiting of blood or material that looks like coffee grounds
- yellow skin or eyes

#### Incidence not known

- Blistering, peeling, or loosening of the skin
- diarrhea
- joint or muscle pain
- · pinpoint red spots on the skin
- red skin lesions, often with a purple center
- red, irritated eyes
- · red, scaling, or crusted skin
- unusual bleeding or bruising

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

#### More common

Bladder pain

- bleeding, blistering, burning, coldness, discoloration of skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at the injection site
- · pounding in the ears

#### Less common

- Abnormal healing
- · decrease in height
- · difficulty with moving
- difficulty with walking
- · dry mouth
- heartburn
- indigestion
- loss of hearing
- loss of strength or energy
- menstrual changes
- muscle or joint stiffness, tightness, or rigidity
- muscle pain or weakness
- · pain in the back, ribs, arms, or legs
- · shakiness in the legs, arms, hands, and feet
- · swelling or redness in the joints

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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