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(For additional information [see "Adalimumab \(including biosimilars of adalimumab\): Drug information"](#) and [see "Adalimumab \(including biosimilars of adalimumab\): Pediatric drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

### **Brand Names: US**

Humira; Humira Pediatric Crohns Start; Humira Pen; Humira Pen-CD/UC/HS Starter; Humira Pen-Pediatric UC Start; Humira Pen-Ps/UV/Adol HS Start; Humira Pen-Psor/Uveit Starter

### **Brand Names: Canada**

Amgevita; Amgevita SureClick; Hadlima; Hadlima PushTouch; Hulio; Humira; Hyrimoz; Idacio

### **Warning**

- Very bad and sometimes deadly infections have happened in patients who take this drug. Most people who had these infections were taking other drugs to lower the immune system like methotrexate or steroid drugs. If you have any infection, are taking antibiotics now or in the recent past, or have had many infections, talk with your doctor.
- TB (tuberculosis) has been seen in patients started on this drug. These patients were exposed to TB in the past, but never got the infection. You will be tested to see if you have been exposed to TB before starting this drug.
- Lymphoma and other cancers have happened in children and teenagers taking this drug or drugs like it. These cancers have also happened in adults. Sometimes, this has been deadly. If you have questions, talk with the doctor.

- A rare type of cancer called hepatosplenic T-cell lymphoma (HSTCL) has happened with this drug and other drugs like it. These cases have been deadly. Almost all cases were in people who were using drugs like this one along with certain other drugs (azathioprine or 6-mercaptopurine). Most of the time, this happened during treatment for Crohn's disease or ulcerative colitis. Also, most cases were in male teenagers or young men. Talk with the doctor.

## **What is this drug used for?**

- It is used to treat some types of arthritis.
- It is used to treat Crohn's disease.
- It is used to treat ankylosing spondylitis.
- It is used to treat plaque psoriasis.
- It is used to treat ulcerative colitis.
- It is used to treat a skin problem called hidradenitis suppurativa.
- It is used to treat uveitis.
- It may be given to you for other reasons. Talk with the doctor.

## **What do I need to tell my doctor BEFORE I take this drug?**

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are taking any of these drugs: Abatacept or anakinra.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking

with your doctor.

## **What are some things I need to know or do while I take this drug?**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- If you have had hepatitis B before or carry the virus, talk with your doctor. Drugs like this one can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems.
- Hepatitis B testing needs to be done as you were told by the doctor. Talk with the doctor.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- Make sure you are up to date with all your vaccines before treatment with this drug.
- Talk with your doctor before getting any vaccines. Use of some vaccines with this drug may either raise the chance of an infection or make the vaccine not work as well.
- Do not get a weakened bacteria like BCG for bladder cancer while you use this drug. Talk with your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- If you have a latex allergy, talk with your doctor. Some products have latex.
- If you have sunburn or other skin problems, talk with your doctor.
- Have your skin checked. Tell your doctor if you have any skin changes like a new wart, skin sore or reddish bump that bleeds or does not heal, or a change in the color or size of a mole.
- Rarely, people using drugs like this one have had nervous system problems.

Sometimes, these problems have not gone away. Call your doctor right away if you have a burning, numbness, or tingling feeling that is not normal; change in eyesight; dizziness; seizures; or weakness in your arms or legs.

- Unsafe blood cell count problems have happened, like aplastic anemia and a type of low white blood cell count. Tell your doctor right away if you feel very tired or weak, or have a fever, chills, shortness of breath, any unexplained bruising or bleeding, or purple "splotches" on your skin.
- If you are 65 or older, use this drug with care. You could have more side effects.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.
- If you used this drug when you were pregnant, tell your baby's doctor.

## **What are some side effects that I need to call my doctor about right away?**

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of infection like fever, chills, very bad sore throat, ear or sinus pain, cough, more sputum or change in color of sputum, pain with passing urine, mouth sores, or wound that will not heal.
- Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.
- Signs of lupus like a rash on the cheeks or other body parts, sunburn easy,

muscle or joint pain, chest pain or shortness of breath, or swelling in the arms or legs.

- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Fever that does not go away.
- A skin lump or growth.
- Pale skin.
- Red scaly patches or bumps that are pus filled.
- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- Liver problems have happened with drugs like this one. Sometimes, this has been deadly. Call your doctor right away if you have signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Heart failure has happened with this drug, as well as heart failure that has gotten worse in people who already have it. Tell your doctor if you have heart disease. Call your doctor right away if you have shortness of breath, a big weight gain, a heartbeat that is not normal, or swelling in the arms or legs that is new or worse.

## **What are some other side effects of this drug?**

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Headache.
- Signs of a common cold.
- Stomach pain.
- Upset stomach.
- Back pain.

- Irritation where the shot is given.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

## How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

### **All products:**

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Wash your hands before and after use.
- Some products must not be shaken. However, you may need to shake some products gently to see the liquid in a viewing window. Be sure you know whether or not to shake this product.
- Do not use if the solution is cloudy, leaking, or has particles.
- Do not give into skin within 2 inches of the belly button.
- Do not give into tender, bruised, red, or hard skin.
- Move the site where you give the shot with each shot.
- To make the injection feel better, take this drug out of the refrigerator and allow it to sit at room temperature for up to 30 minutes before use. Do not remove the cap or cover. Do not heat this drug.
- Different brands of this drug may be clear or have a slight color. Be sure you know what your brand needs to look like when ready to use. Do not use if the solution changes color. If you are not sure, talk with the pharmacist.

- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

**Auto-injectors, prefilled pens, and prefilled syringes:**

- Throw syringe away after use. Do not use the same syringe more than one time.

**Vials:**

- Throw away any part of the opened vial not used after the shot is given.

## **What do I do if I miss a dose?**

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you are not sure what to do if you miss a dose, call your doctor.

## **How do I store and/or throw out this drug?**

- Store in a refrigerator. Do not freeze.
- Do not use if it has been frozen.
- Store in the original container to protect from light.
- If needed, you may store at room temperature for up to 14 days. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used within 14 days, throw this drug away.
- Protect from heat.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down

a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

## **General drug facts**

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

## **Last Reviewed Date**

2020-08-06

## **Consumer Information Use and Disclaimer**

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this



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