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(For additional information see "Infliximab (including biosimilars of infliximab): Drug information" and see "Infliximab (including biosimilars of infliximab): 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

Avsola; Inflectra; Remicade; Renflexis

Brand Names: Canada

Avsola; Inflectra; Remicade; Renflexis

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 people who take this drug or drugs like it. This has been deadly in some cases. 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 Crohn's disease.
- It is used to treat some types of arthritis.
- It is used to treat plaque psoriasis.
- It is used to treat ankylosing spondylitis.
- It is used to treat ulcerative colitis.
- 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 allergic to mouse proteins, talk with the doctor.
- If you have heart failure (weak heart).
- If you are taking any of these drugs: Abatacept, anakinra, or tocilizumab.
- 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.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Low blood cell counts have happened with this drug. If blood cell counts get very low, this can lead to bleeding problems, infections, or anemia. Sometimes, these have been deadly. If you have questions, talk with the doctor.
- You may have more chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu.
- 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 raise the chance of an infection.
- Do not get a weakened bacteria like BCG for bladder cancer while you use this drug. 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.
- If you have had hepatitis B before or carry the virus, this drug can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems. You will be tested for hepatitis B before starting this drug. You will need to watch for signs of hepatitis while taking this drug and for several months after stopping it. Talk with your doctor.
- 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.
- Liver problems have rarely happened with this drug. 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.

- Abnormal heartbeats, heart attacks, high or low blood pressure, and strokes
 have happened during and within 24 hours after the infusion. Sometimes,
 heart attacks have been deadly. Loss of eyesight has also happened during and
 within 2 hours after the infusion. Talk with the doctor.
- If you are 60 or older, use this drug with care. You could have more side effects.
- If the patient is a child, use this drug with care. The risk of some side effects may be higher in children.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breastfeeding. You will need to talk about the benefits and risks to you and the baby.
- If you used this drug during pregnancy, tell your baby's doctor. You will need to discuss the safety and timing of certain vaccines with the 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 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 or low blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Redness or swelling where the shot is given.
- Any unexplained bruising or bleeding.
- Pale skin.
- · Loss of eyesight.
- · A skin lump or growth.
- Vaginal bleeding that is not normal.
- · Fast or slow heartbeat.
- Red scaly patches or bumps that are pus filled.
- Fever, chills, itching, hives, chest pain or pressure, or shortness of breath when drug is given. Other drugs may be given to avoid these.
- Call your doctor right away if you have a swollen gland, night sweats, shortness of breath, or weight loss without trying.
- 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.
- Upset stomach or throwing up.

- Stomach pain or diarrhea.
- · Feeling tired or weak.
- · Flushing.
- Signs of a common cold.

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.

- It is given as an infusion into a vein over a period of time.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.

What do I do if I miss a dose?

• Call your doctor to find out what to do.

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

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

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.
- 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.
- 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

2020-07-13

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 medicine. The use of this information is governed by the Lexicomp End User

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Topic 10762 Version 146.0