Memorial Sloan Kettering Cancer Center

PATIENT & CAREGIVER EDUCATION

Golimumab

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US
Simponi; Simponi Aria

Brand Names: Canada
Simponi; Simponi I.V.

Warning

- This drug may raise the chance of infection, including severe infections. Sometimes severe infections have led to death. 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 in people taking drugs like this one. This cancer has been deadly. Almost all cases happened during treatment for Crohn's disease or ulcerative colitis. Most of these people were male teenagers or young males. Almost all of the people were also taking certain other drugs (azathioprine or mercaptopurine). If you have questions, talk with the doctor.

What is this drug used for?

- It is used to treat some types of arthritis.
- 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 have an infection.
- If you are taking any of these drugs: Abatacept, adalimumab, anakinra, certolizumab, etanercept, infliximab, rituximab, or tocilizumab.

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.

- If you have a latex allergy, talk with your doctor. Some products have latex.
- Have your blood work and other lab tests checked as you have been told by your doctor.
- 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.
- If possible, make sure all vaccines are up to date 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 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.

- Allergic reactions have happened with this drug. Some reactions may be severe or life-threatening. This can happen even after the first dose. Call your doctor right away if you have any signs that are not normal.
- If giving this drug to your child and your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.
- 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. Your baby may have a higher chance of getting an infection for at least 6 months after birth. Your baby's doctor will also need to decide when your baby is to get any vaccines. Certain vaccines may cause infections that can lead to very bad health problems or death if given within 6 months after birth.

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 liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- 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.
- Chest pain or pressure.
- Feeling very tired or weak.
- Any unexplained bruising or bleeding.
- Pale skin.

- Red scaly patches or bumps that are pus filled.
- A skin lump or growth.
- Flu-like signs.
- Warm, red, or painful skin or sores on the body.
- 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. Sometimes, this has been deadly. 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.
- 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.

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:

- Bruising, itching, pain, redness, swelling, or other reaction where the injection was given.
- 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.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

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

Prefilled syringes and auto-injectors:

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.
- If using the prefilled syringe, it may also be given into the outer area of the upper arm if given by someone else.

- If using the auto-injector, do not give the shot into the arm.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- If stored in a refrigerator, let this drug come to room temperature before using it. Leave it at room temperature for at least 30 minutes. Do not heat this drug.
- Do not shake the solution.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- This drug is clear to slightly pearly. Some products may contain small white or clear particles. If you see white or clear particles, be sure you know if you can use your drug. You may also see one or more air bubbles. Do not use if the solution is cloudy, leaking, or has large particles.
- Do not give into skin within 2 inches (5 cm) of the belly button.
- Do not give into skin that is irritated, tender, bruised, red, scaly, hard, scarred, or has stretch marks.
- Wash your hands before and after use.
- Use within 5 minutes of taking off the needle cover.

- Move the site where you give the shot with each shot.
- If the dose is more than 1 injection, give the injections into 2 different places.
- Do not rub the site where you give the shot.
- Throw syringe away after use. Do not use the same syringe more than one time.
- 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.
- Do not use the prefilled syringe if it has been dropped or if it is broken. Do not use the autoinjector if it has been dropped without the cap on or if it is damaged. Check with your pharmacist if you drop this drug and are not sure what to do.

Vials (for IV infusion):

- It is given as an infusion into a vein over a period of time.

What do I do if I miss a dose?
Prefilled syringes and auto-injectors:

- Take a missed dose as soon as you think about it 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.

Vials (for IV infusion):

- Call your doctor to find out what to do.

How do I store and/or throw out this drug?
Simponi prefilled syringes and auto-injectors:

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.
- If needed, you may store at room temperature for up to 30 days. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not used within 30 days, throw this drug away.
- If stored at room temperature, make a note of the date it was placed at room temperature.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.

Immgolis prefilled syringes:

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.
- If needed, you may store at room temperature for up to 15 days. Write down the date you take this drug out of the refrigerator. If stored at room temperature and not

used within 15 days, throw this drug away.

- If stored at room temperature, make a note of the date it was placed at room temperature.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.

Vials (for IV infusion):

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

All products:

- 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.

- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, 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.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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