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 your child has any infection, is taking antibiotics now or in the recent past, or has had many infections, talk with your child's 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. The doctor may test to see if your child has 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 ulcerative colitis.
- It may be given to your child for other reasons. Talk with the doctor.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has an infection.
- If your child is 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 the doctor and pharmacist about all of your child's drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe to give this drug with all of your child's other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

What are some things I need to know or do while my child takes this drug?

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists.
- If your child has a latex allergy, talk with the doctor. Some products have latex.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- If your child has had hepatitis B before or carries the virus, this drug can cause the virus to become active. This can lead to very bad and sometimes deadly liver problems. Your child will be tested for hepatitis B before starting this drug. You will need to watch for signs of hepatitis while your child takes this drug and for several months after your child stops it. Talk with your child's doctor.
- If possible, make sure all vaccines are up to date before treatment with this

drug.

- Talk with the doctor before your child gets any vaccines. Use of some vaccines with this drug may either raise the chance of very bad infection or make the vaccine not work as well.
- Be sure your child does not get a weakened bacteria like BCG for bladder cancer while using this drug. Talk with the doctor.
- Have your child's skin checked. Tell your child's doctor if your child has 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 the doctor right away if your child has 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 your child is pregnant or breast-feeding a baby:

- Talk with the doctor if your child is pregnant, becomes pregnant, or is breast-feeding a baby. You will need to talk about the benefits and risks to your child and the baby.
- If your child used this drug when she was pregnant, tell the baby's doctor. The baby may have a higher chance of getting an infection for at least 6 months after birth. The baby's doctor will also need to decide when the 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 child's 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 child's doctor or get medical help right away if your child has 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 child's doctor right away if your child has 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 the doctor if your child has heart disease. Call the doctor right away if your child has 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 the doctor right away if your child has a burning, numbness, or tingling feeling that is not normal; change in eyesight; dizziness; seizures; or weakness in the 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child 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 child's doctor. Call your child's doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's 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, belly area, or upper arm.
- If using the auto-injector, do not give the shot into the arm.
- If you will be giving your child the shot, your child's 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 my child misses a dose?

Prefilled syringes and auto-injectors:

- Give a missed dose as soon as you think about it and go back to your child's normal time.
- Do not give 2 doses at the same time or extra doses.
- If you are not sure what to do if your child misses a dose, call the doctor.

Vials (for IV infusion):

- Call your child's doctor to find out what to do.

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

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.

Vials (for IV infusion):

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

General drug facts

- If your child's symptoms or health problems do not get better or if they become worse, call your child's doctor.

- Do not share your child's drug with others and do not give anyone else's drug to your child.
- 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 child's 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.

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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 provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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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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