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(For additional information <u>see "Ustekinumab: Drug information"</u> and <u>see "Ustekinumab: Pediatric drug information"</u>)

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

Brand Names: US

Stelara

Brand Names: Canada

Stelara

What is this drug used for?

- It is used to treat plaque psoriasis.
- It is used to treat psoriatic arthritis.
- It is used to treat Crohn's disease.
- It is used to treat ulcerative colitis.

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 had the BCG vaccine in the past year.
- If you have an infection.
- If you have active TB (tuberculosis).

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 blood work checked as you have been told by the doctor. Talk with the doctor.
- Drugs that may suppress the immune system like this drug may raise the risk of cancer. If you have questions, talk with the 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.
- You may have more of a chance of getting an infection. Wash hands often. Stay away from people with infections, colds, or flu. Some infections have been very bad and even deadly.
- Talk with your doctor before getting any vaccines while you take this drug and after you stop taking it. Vaccine use with this drug may either raise the chance of an infection or make the vaccine not work as well. Talk with your doctor.
- You will need a TB (tuberculosis) test before starting this drug.
- If your weight changes, talk with your doctor. The dose of this drug may need to be changed.
- If you are 60 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 breastfeeding. You will need to talk about the benefits and risks to you and the baby.

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.
- Warm, red, or painful skin or sores on the body.
- · Shortness of breath.
- Flushing.
- Very bad dizziness or passing out.
- A skin lump or growth.
- Vaginal itching or discharge.
- A very bad and sometimes deadly brain problem called posterior reversible encephalopathy syndrome (PRES) has happened with this drug. Call your doctor right away if you have signs like feeling confused, lowered alertness, change in eyesight, loss of eyesight, seizures, or very bad headache.
- Pneumonia has happened during use of this drug. Sometimes this has been serious, and people have needed to go to the hospital. Tell your doctor if you have cough, fever, chest pain, shortness of breath, or trouble breathing.

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:

- Feeling tired or weak.
- · Headache.
- Upset stomach or throwing up.
- Stomach pain or diarrhea.
- Nose or throat irritation.
- Signs of a common cold.
- 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.

<u>Prefilled syringes or vials (subcutaneous injection):</u>

- It is given as a shot into the fatty part of the skin in the upper arm, thigh, buttocks, or stomach 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.
- Move the site where you give the shot with each shot.

- This product may contain small white particles. Do not use if the solution is cloudy, leaking, or has large lumps, flakes, or other particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Do not give into skin that is irritated, bruised, red, infected, or scarred.
- · Do not shake.
- Each prefilled syringe or vial is for one use only. Throw away any part left over after the dose is given.
- 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.

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?

• Call your doctor to find out what to do.

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

<u>Prefilled syringes or vials (subcutaneous injection):</u>

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.

Vials:

• Store upright with the cap on.

Prefilled syringes:

- If needed, you may store at room temperature for up to 30 days. If stored at room temperature and not used within 30 days, throw this drug away.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.

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.
- 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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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 License Agreement, available at

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