PART III: CONSUMER INFORMATION

Pr STELARA®
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ustekinumab Solution for Subcutaneous Injection

Read this carefully before you start taking STELARA® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your doctor or pharmacist about your medical condition and treatment and ask if there is any new information about STELARA®.

ABOUT THIS MEDICATION

What is STELARA® used for:

Adults with Plaque Psoriasis
STELARA® is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

Children 12 to 17 years of age with Plaque Psoriasis
STELARA® is a prescription medicine that is approved for adolescent patients from the age of 12 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

Adults with Psoriatic Arthritis
STELARA® is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given STELARA® by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking and climbing stairs) and improve your psoriasis.

Adults with Crohn's disease
STELARA®/STELARA® I.V. is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease. For patients with Crohn's disease, the first dose, STELARA® I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of STELARA® are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. If you have moderately to severely active Crohn's disease that has not responded to other medications and you are an adult, you may be given STELARA®/STELARA® I.V. to help relieve your symptoms and keep the disease under control. STELARA®/ STELARA® I.V. may help reduce or stop the use of your corticosteroid medication.

How does STELARA® work?
STELARA® blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis or Crohn's disease, their immune system may attack parts of their body and that attack uses IL-12 and IL –23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

Do not use STELARA® if:
- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to STELARA®, STELARA® I.V., or any of the other ingredients in STELARA®. See below for a complete list of ingredients in STELARA®.
- after the expiration date on the label;
- the seal is broken;
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it;
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated);

You should not receive a live vaccine while taking STELARA®.

Always keep medicine out of the reach of children.

What the medicinal ingredient is:
ustekinumab

What the important nonmedicinal ingredients are:
STELARA® 45 mg or 90 mg for injection under the skin. The inactive ingredients include sucrose, L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 and water for injection. No preservatives are present.

STELARA® comes in the following dosage forms:
Pre-filled Syringe:
- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:
- 45 mg / 0.5 mL

ǂ 90 mg/1.0 mL single-use vial is not available in Canada.

WARNINGS AND PRECAUTIONS

Your doctor will assess your health before each treatment.

To help avoid side effects and ensure proper use, talk to your doctor or pharmacist BEFORE you take STELARA®. Talk to your doctor or pharmacist about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to STELARA® or STELARA® I.V. Ask your doctor if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions
- have recently received or are scheduled to receive a vaccine. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system, and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, planning to become pregnant, or breastfeeding.

Contact your doctor immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

The needle cover on the pre-filled syringe contains dry natural rubber (a form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your doctor if you have ever had an allergic reaction to latex and developed any allergic reaction to STELARA® injection.

STELARA® should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use STELARA®.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

INTERACTIONS WITH THIS MEDICATION

STELARA® may change the way the body responds to live vaccines.

STELARA® may interact with other medications that decrease the activity of the immune system.

If you have questions ask your health care provider.

PROPER USE OF THIS MEDICATION

Psoriasis

For treatment of psoriasis, STELARA® is given by injection under the skin.

Adults:

The recommended dose of STELARA® is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your doctor may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg.

Pediatric Psoriasis (12 years of age or older)

The recommended dose of STELARA® based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of STELARA®
< 60kg	0.75 mg/kg
≥ 60 to ≤ 100 kg	45 mg
> 100 kg	90 mg

In children 12 to 17 of age with psoriasis, it is recommended that STELARA® be administered by a health care provider. If your doctor determines that it is appropriate, you may be able to administer STELARA® to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "Instructions for injecting STELARA® under the skin yourself".)

Psoriatic Arthritis

For treatment of psoriatic arthritis, STELARA® is given by injection under the skin. The recommended dose of STELARA® is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's disease

For treatment of Crohn's disease, the recommended dose is a single intravenous dose of STELARA® I.V. based on body weight (as shown below) followed by 90 mg STELARA® given by injection under the skin (subcutaneous).

Weight	Recommended Dose of STELARA® I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (STELARA® I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (STELARA®)
Further treatment	Every 8 weeks or every 12 weeks Subcutaneous injection (STELARA®)

The BioAdvance® Network has been established to facilitate the administration of STELARA®. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of STELARA®. Contact your doctor if you have any questions.

Overdose:
Call your doctor if you accidentally inject STELARA® more frequently than instructed.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
If you miss a dose, contact your healthcare provider for guidance.

Instructions for injecting STELARA® under the skin yourself:

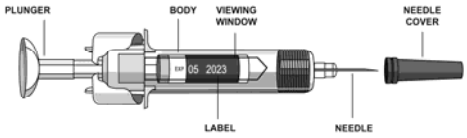
STELARA® may be injected by your healthcare provider. In children 12 to 17 years of age, it is recommended that all doses of STELARA® be administered by a health care provider. However, your doctor may decide that it is right for you or your caregiver to learn how to inject STELARA® under the skin (subcutaneously) yourself. Before you self-inject STELARA®, you must be trained by a healthcare professional. If you have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. STELARA® is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING STELARA® USING A PRE-FILLED SYRINGE

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake STELARA® at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

1: PREPARING FOR PRE-FILLED SYRINGE USE



Take the Syringe out of the Refrigerator
If your dose amount is 90 mg and you receive two 45 mg packages, you need to give a second injection right after the first. Choose a different site for the second injection. Children who weigh 60 kg or more may use the prefilled syringe.

Check Expiration Date
Open the box and remove the pre-filled syringe. Check the expiration date on the pre-filled syringe and the label of the box. If the expiration date has passed, don't use it.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

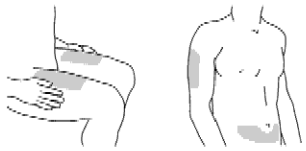
Check Solution in Syringe
Hold the pre-filled syringe with the covered needle pointing upward. Make sure the syringe is not damaged. Look at the solution or liquid in the syringe to make sure that it is clear to slightly opalescent and colorless to slightly yellow. DO NOT use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

DO NOT remove the needle cover from the pre-filled syringe.

DO NOT pull back on the plunger head at any time.

2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.

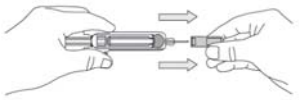


*Areas in gray are recommended injection sites.

Prepare the Injection Site
Thoroughly wash your hands with soap and warm water. Wipe

the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

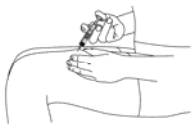
3: INJECTING THE MEDICATION



Remove the Needle Cover
When you are ready to inject, pick up the pre-filled syringe, hold the body of the syringe with one hand and pull the needle cover straight off. Throw the needle cover into the trash. You may notice a small air bubble in the pre-filled syringe. You do not need to remove the air bubble. You may also see a drop of liquid at the end of the needle – this is normal. Do not touch the needle or allow it to touch any surface.

Note: The needle cover should NOT be removed until you are ready to inject the dose. Do not use syringe if it is dropped without the needle cover in place. If you drop the syringe without the needle cover in place, please contact your healthcare provider for assistance.

Inject the Medication
Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.



Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid.

Push it slowly and evenly, keeping the skin pinched.

When the plunger meets the end of the syringe barrel, and all of the medication has been injected, release the pinched skin and gently remove the needle. Following complete injection, the needle guard will automatically extend over the needle and lock as you take your hand off the plunger.

4: AFTER THE INJECTION

Dispose of the Empty Syringe
Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, needles and syringes **must NEVER** be re-used. Dispose of sharps container according to your local regulations.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

INSTRUCTIONS FOR INJECTING STELARA® FROM A 45 mg/0.5 mL or 90mg/1.0mL VIAL‡

‡90 mg/1.0 mL single-use vial is not available in Canada.

Do not shake STELARA® Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. STELARA® is not to be mixed with other liquids for injection.

1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

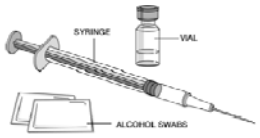
Take the Vial(s) out of the Refrigerator
If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive either one 90 mg vial or two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date
Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

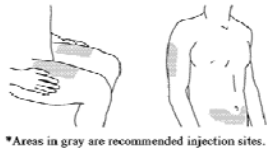
Check Solution in Vial
Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear to slightly opalescent and colorless to slightly yellow. **DO NOT** use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

Assemble Additional Supplies
Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.



2: CHOOSING AND PREPARING THE INJECTION SITE

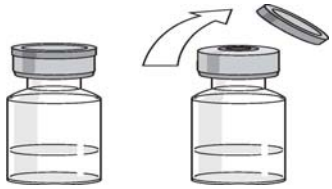
Choose the Injection Site*
Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.


*Areas in gray are recommended injection sites.

Prepare the Injection site
Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: PREPARING THE DOSE

Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.



Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.

Put the vial on a flat surface and push the syringe needle through the rubber stopper.

Turn the vial and the syringe upside down.
For adults and children 12 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider (0.5 mL to 1.0 mL). It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 12 to 17 years of age who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.

Remove the needle from the vial
Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.

4: INJECTING THE MEDICATION

Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.

Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.

When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

Press an antiseptic wipe over the injection site for a few seconds after the injection.

Dispose the Empty Syringe and Vial(s)
Discard any unused portion of STELARA®. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

Use a Cotton Ball or Gauze
There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of STELARA® are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given

STELARA® is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- STELARA® may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using STELARA®. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your doctor will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with STELARA® and during treatment with STELARA®.

Cancers

- STELARA® may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your doctor if you notice any unusual changes to your skin or health status while receiving STELARA® treatment.

Serious Skin Conditions
Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your doctor immediately if you notice any of these signs.

SERIOUS SIDE EFFECTS, HOW OFTEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor immediately
		Only if severe	In all cases	
Very Common	Infected nose, sinuses or throat (cold)	√		
Common	Sore throat, nasal congestion	√		
	Allergic reaction (skin rash)		√	
Uncommon	Cellulitis (skin infection)		√	
	Vaginal yeast infections	√		
	Tooth abscess/tooth infection	√		
Rare	Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			√
	Increase in redness and shedding of skin		√	

Very common: at least 1 in 10 patients; Common: at least 1 in 100 and less than 1 in 10 patients; Uncommon: at least 1 in 1,000 and less than 1 in 100 patients; Rare: at least 1 in 10,000 and less than 1 in 1000.

In general, the side effects of STELARA® seen in children 12 to 17 years of age are similar to those in adults.

This is not a complete list of side effects. For any unexpected effects while taking STELARA®, contact your doctor or pharmacist.

HOW TO STORE IT

If you are using STELARA® at home, it is important to store the product in your refrigerator at 2-8°C (36-46°F) although not in the freezer compartment. STELARA® should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

Always keep medicine out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full product monograph go to: www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

Last revised: November 2018

PART III: CONSUMER INFORMATION

Pr STELARA® I.V.
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ustekinumab Intravenous Infusion

Read this carefully before you start taking STELARA® I.V. This leaflet is a summary and will not tell you everything about this drug. Talk to your doctor or pharmacist about your medical condition and treatment and ask if there is any new information about STELARA® I.V.

ABOUT THIS MEDICATION

What is STELARA® I.V. used for:

Adults with Crohn's disease
STELARA® I.V./STELARA® is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease. For patients with Crohn's disease, the first dose, STELARA® I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of STELARA® are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. If you have moderately to severely active Crohn's disease that has not responded to other medications and you are an adult, you may be given STELARA® I.V./STELARA® to help relieve your symptoms and keep the disease under control. STELARA® I.V./ STELARA® may help reduce or stop the use of your corticosteroid medication.

How does STELARA® I.V. work?
STELARA® I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease, their immune system may attack parts of their body and that attack uses IL-12 and IL –23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the digestive tract.

Do not use STELARA® I.V. if:
- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to STELARA® I.V. or STELARA® or any of the other ingredients in STELARA® I.V. See below for a complete list of ingredients in STELARA® I.V.
- after the expiration date on the label;
- the seal is broken;
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it;
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated);

You should not receive a live vaccine when taking STELARA® I.V.

What the medicinal ingredient is:
ustekinumab

What the important nonmedicinal ingredients are:
The inactive ingredients include: sucrose, L-histidine and L-histidine hydrochloride monohydrate, polysorbate 80, L-methionine, and EDTA disodium salt dihydrate. No preservatives are present.

STELARA® I.V. comes in the following dosage forms:
STELARA® I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg ustekinumab in 26 mL.

WARNINGS AND PRECAUTIONS

Your doctor will assess your health before each treatment.

To help avoid side effects and ensure proper use, talk to your doctor or pharmacist BEFORE you take STELARA® I.V. Talk to your doctor or pharmacist about any health conditions or problems you may have, including if you:
- ever had an allergic reaction to STELARA® I.V. or STELARA®. Ask your doctor if you are not sure.
- have any kind of infection even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing skin lesions
- have recently received or are scheduled to receive a vaccine. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system, and can cause serious problems.
- are receiving or have received "allergy shots", especially for serious allergic reactions.
- are pregnant, planning to become pregnant, or breastfeeding.

Contact your doctor immediately:
- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

STELARA® I.V. should only be used during a pregnancy if needed. Women who are breastfeeding should talk to their doctor about whether or not to use STELARA® I.V.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

INTERACTIONS WITH THIS MEDICATION

STELARA® I.V. may change the way the body responds to live vaccines.

STELARA® I.V. may interact with other medications that decrease the activity of the immune system.

If you have questions ask your health care provider.

PROPER USE OF THIS MEDICATION

Crohn's disease

For treatment of Crohn's disease, the recommended dose is a single intravenous dose of STELARA® I.V. based on body weight (as shown below) followed by 90 mg STELARA® given by injection under the skin (subcutaneous).

Weight	Recommended Dose of STELARA® I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (STELARA® I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (STELARA®)
Further treatment	Every 8 weeks or every 12 weeks Subcutaneous injection (STELARA®)

The initial dose of STELARA® I.V. for intravenous infusion for Crohn's disease will be given over a period of at least one hour.

The BioAdvance® Network has been established to facilitate the administration of STELARA® I.V. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of STELARA® I.V. infusions. Contact your doctor if you have any questions.

Overdose:
In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse effects and appropriate symptomatic treatment be instituted immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects of STELARA® I.V. are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given

STELARA® I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- STELARA® I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using STELARA® I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your doctor will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with STELARA® I.V.

Cancers

- STELARA® I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your doctor if you notice any unusual changes to your skin or health status while receiving STELARA® I.V. treatment.

Serious Skin Conditions

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should contact your doctor immediately if you notice any of these signs.

SERIOUS SIDE EFFECTS, HOW OFTEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor immediately
		Only if severe	In all cases	
Very Common	Infected nose, sinuses or throat (cold)	√		
Common	Sore throat, nasal congestion	√		
	Allergic reaction (skin rash)		√	
Uncommon	Cellulitis (skin infection)		√	
	Vaginal yeast infections	√		
	Tooth abscess/tooth infection	√		
Rare	Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			√
	Increase in redness and shedding of skin		√	

Very common: at least 1 in 10 patients; Common: at least 1 in 100 and less than 1 in 10 patients; Uncommon: at least 1 in 1,000 and less than 1 in 100 patients; Rare: at least 1 in 10,000 and less than 1 in 1000.

This is not a complete list of side effects. For any unexpected effects while taking STELARA® I.V., contact your doctor or pharmacist.

HOW TO STORE IT

STELARA® I.V. must be stored in the original package in the refrigerator at 2-8°C (36-46°F) before use. STELARA® I.V. should not be frozen. It must be kept out of the reach and sight of children. Keep the product in its original carton to protect from light until the time of use. Do not shake.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 1908C
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full product monograph go to: www.janssen.com/canada or contact the manufacturer, Janssen Inc., at 1-800-567-3331, or 1-800-387-8781.

This leaflet was prepared by Janssen Inc., Toronto, Ontario M3C 1L9

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