

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**WEZLANA**™ (pronounced *wez-LAHN-uh*)

ustekinumab injection

Solution for Subcutaneous Injection

Prefilled Syringe / Single-use Vial

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

Wezlana is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is Wezlana used for?

- **Adults with Plaque Psoriasis**

Wezlana is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

Wezlana is a prescription medicine that is approved for children and adolescent patients 6 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**

Wezlana 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 Wezlana 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 or ulcerative colitis**

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

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

Wezlana / Wezlana I.V. may help reduce or stop the use of your corticosteroid medication.

How does Wezlana work?

Wezlana 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, Crohn's disease or ulcerative colitis, 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.

What are the ingredients in Wezlana?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose. No preservatives are present.

Wezlana comes in the following dosage forms:

Prefilled Syringe:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:

- 45 mg / 0.5 mL

Prefilled ConfiPen™ Autoinjector:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Do not use Wezlana 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 Wezlana, Wezlana I.V., or any of the other ingredients in Wezlana (see What are the ingredients in Wezlana? section). You should not receive a live vaccine when taking Wezlana I.V.

If you used Wezlana I.V. while pregnant, tell your baby's healthcare professional about your Wezlana I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Wezlana. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Wezlana or Wezlana I.V. Ask your healthcare professional 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 healthcare professional 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, think you might be pregnant, planning to become pregnant, or breast-feeding. Ustekinumab may pass into your breast milk in small amounts.

Contact your healthcare professional 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).

There is limited experience with ustekinumab in pregnant and breast-feeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Wezlana and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breast-feeding your healthcare professional will help you decide whether or not to use Wezlana.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Wezlana:

- Wezlana may change the way the body responds to live vaccines. You should not receive a live vaccine while taking Wezlana.
- Wezlana may interact with other medications that decrease the activity of the immune system.

How to take Wezlana:

Wezlana may be injected by your healthcare professional. In children 6 to 17 years of age, it is recommended that all doses of Wezlana be administered by a healthcare professional. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject Wezlana under the skin (subcutaneously) yourself. Before you self-inject Wezlana, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare professional to schedule a training session. Call your healthcare professional if you have any questions about giving yourself an injection. Wezlana is not to be mixed with other liquids for injection.

Usual dose:**Psoriasis**

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

Adults:

The recommended dose of Wezlana is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional 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 (6 years of age or older):

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

Weight	Recommended dose of Wezlana	Dosage Form
< 60 kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Prefilled syringe, vial, prefilled ConfiPen autoinjector
> 100 kg	90 mg	Prefilled syringe, prefilled ConfiPen autoinjector

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL / kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of Wezlana for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24

Injection volumes of Wezlana for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 years of age with psoriasis, it is recommended that Wezlana be administered by a healthcare professional. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer Wezlana to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected.

Psoriatic Arthritis

For treatment of psoriatic arthritis, Wezlana is given by injection under the skin. The recommended dose of Wezlana 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 and ulcerative colitis

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

Weight	Recommended Dose of Wezlana 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 and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Wezlana I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Wezlana)
Further treatment	Every 8 weeks* Subcutaneous injection (Wezlana)

*Your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The Entrust™ Patient Support Services facilitate the administration of Wezlana through the Entrust™ Infusion Network with clinics staffed by qualified healthcare professionals specially trained in the administration of Wezlana infusions. Information about the Entrust™ Patient Support Services can be obtained by calling 1-877-936-2735.

Overdose:

Call your healthcare professional if you accidentally inject Wezlana more frequently than instructed.

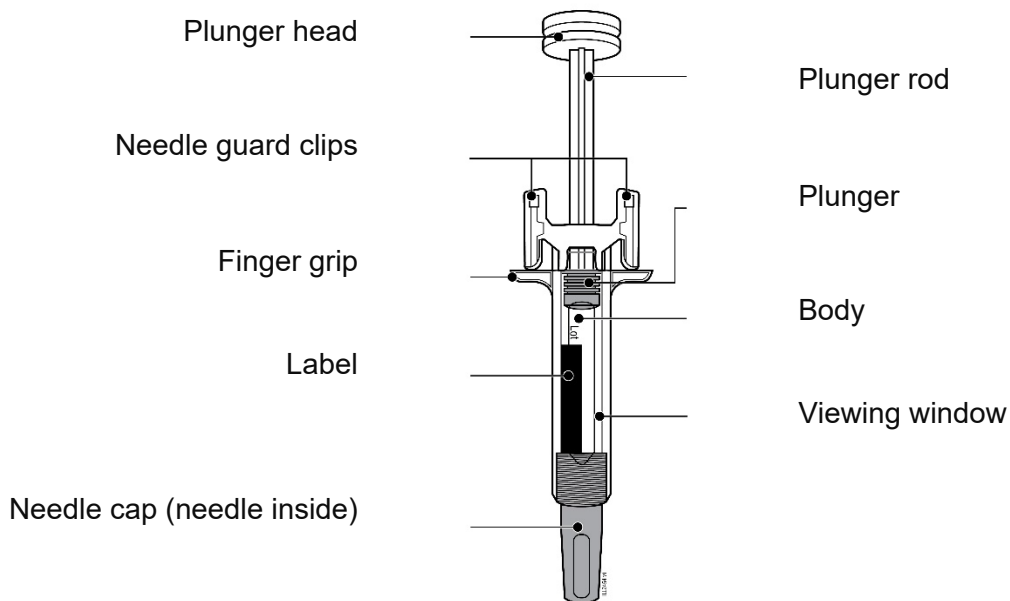
If you think you, or a person you are caring for, have taken too much Wezlana, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, contact your healthcare professional for guidance.

INSTRUCTIONS FOR INJECTING Wezlana USING A PREFILLED SYRINGE:

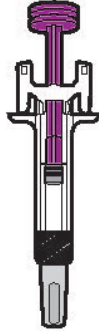
Getting to know your prefilled syringe



- **IMPORTANT INFORMATION** you need to know before injecting Wezlana with a prefilled syringe

Dosing:

- Wezlana comes in two different doses: 45 mg / 0.5 mL and 90 mg / 1.0 mL. Check your prescription to make sure you have the correct dose.
- The look of the prefilled syringe will be different for each dose. The amount of medicine in the syringe will also be different for each dose.
- For example, it is okay for the 45 mg / 0.5 mL dose to have a small amount of medicine and the 90 mg / 1.0 mL to have a large amount of medicine. Check the illustrations below to see what your dose looks like in the syringe.



45 mg / 0.5 mL



90 mg / 1.0 mL

Using your Wezlana prefilled syringe:

- It is important that you do not try to give the injection until you have fully read and understood these instructions for use.
- Do NOT use the syringe if the carton is damaged or the seal is broken.
- Do NOT use the syringe after the expiration date on the label.
- Do NOT shake the syringe.
- Do NOT remove the needle cap from the syringe until you are ready to inject.
- Do NOT use the syringe if it has been frozen.
- Do NOT use the syringe if it has been dropped on a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new syringe and call 1-866-502-6436.
- The syringe and its components are not made with natural rubber latex.

Important: Keep the syringe and sharps disposal container out of the sight and reach of children.

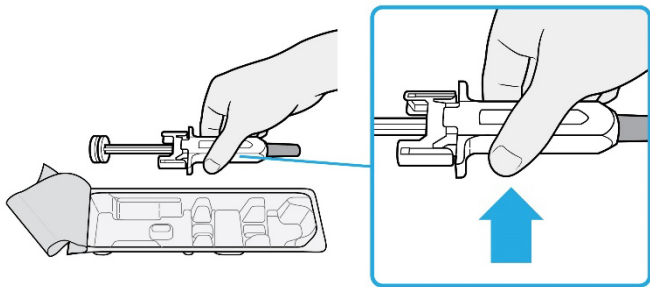
- Storing and preparing to inject Wezlana

2a. Refrigerate the syringe carton until you are ready to use.

- Keep the syringe in the refrigerator between 2°C to 8°C.
- Keep the syringe in the original carton to protect from light or physical damage.
- Do NOT freeze.
- Do NOT store the syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the syringe out of the sight and reach of children.

2b. Grasp syringe by the body and remove from carton.



- Do NOT grab the plunger rod, finger grip, or the needle cap.
- Do NOT grab the needle guard clips.

2c. Wait 30 minutes for the syringe to reach room temperature.

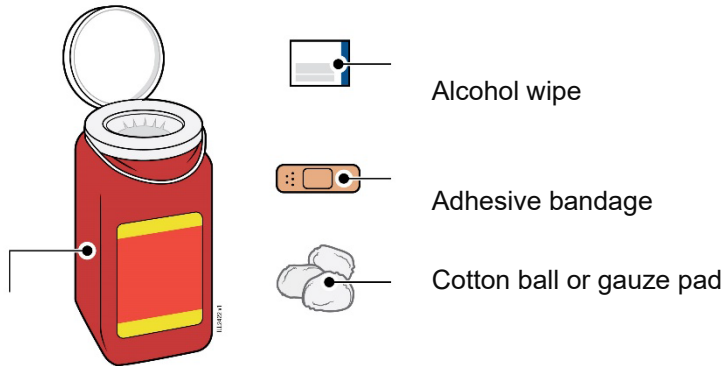
- Let the syringe warm up naturally.
- Do NOT heat with hot water, a microwave, or direct sunlight.
- Do NOT shake the syringe at any time.
- Using the syringe at room temperature allows for a more comfortable injection.

2d. You may keep at room temperature for up to 30 days, if needed.

- For example, when you are travelling, you may keep Wezlana at room temperature.
- Keep it at room temperature up to 30°C.
- Do NOT use if the syringe has been stored above 30°C.
- Do NOT put back in refrigerator.
- Record the date you removed it from the refrigerator and use within 30 days.

Important: Place the syringe in a sharps container if it has reached room temperature and has not been used within 30 days.

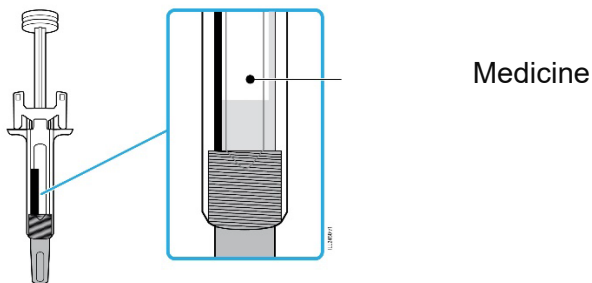
2e. Gather and place items for your injection on a clean, well-lit surface.



Sharps disposal container

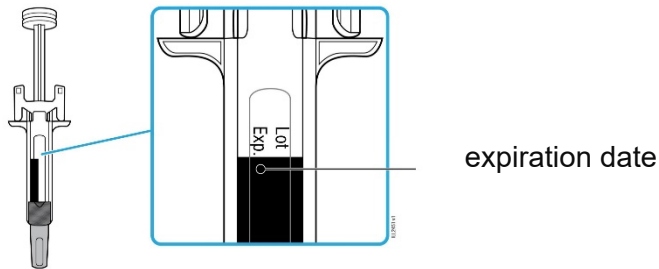
- Wezlana syringe (room temperature)
- Sharps disposal container (see [5 Disposing & finishing Wezlana](#))
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad
- Getting ready for your injection

3a. Inspect the medicine. It should be clear and colourless to slight yellow.



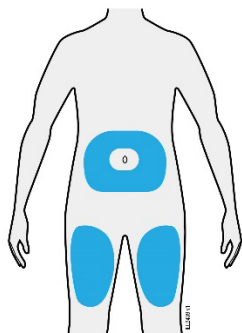
- It is okay to see air bubbles.
- Do NOT use if the medicine is frozen, cloudy, discoloured or has large particles.

3b. Check the expiration date (EXP) and inspect the syringe.



- Do NOT use if expiration date has passed.
- Do NOT use the syringe if:
 - The cap is missing or loose.
 - It has cracks or broken parts.
 - It has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

3c. Inject in one of these locations



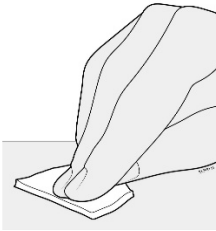
- Inject in your thigh or stomach (except for the 5 cm (2 inch) area around your belly button).
- Choose a different site for each injection.
- Someone else can inject in your thigh, stomach, back of the upper arm, or buttocks.

Important: Avoid areas with scars, stretch marks or where skin is tender, bruised, red or hard.

3d. Wash hands thoroughly with soap and water.

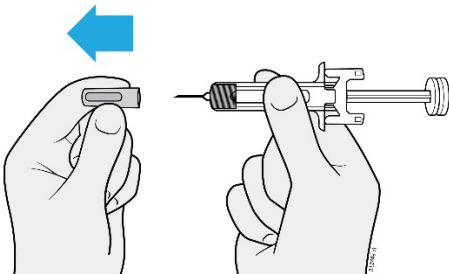


3e. Clean injection site with an alcohol wipe.



- Let your skin dry on its own.
- Do NOT touch this area again before injecting.
- Injecting Wezlana

4a. Pull the needle cap straight off while holding the syringe body.



Important: Only remove the cap when you can inject right away (within 5 minutes) because the medicine can dry out.

- Do NOT twist or bend the needle cap.
- Never put the cap back on. It may damage the needle.
- Do NOT let anything touch the needle once the cap is removed.
- Do NOT place the uncapped syringe on any surface once the cap is removed.
- Do NOT try to push air bubbles out. It is okay to see air bubbles.
- If a drop of liquid is at the end of the needle, it is normal.

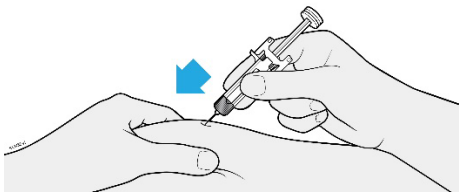
4b. Pinch the skin around the injection site before injection.



- Pinch the skin between thumb and index finger to create a bump for the injection.
- If possible, the bump should be about 5 cm (2 inches) wide.

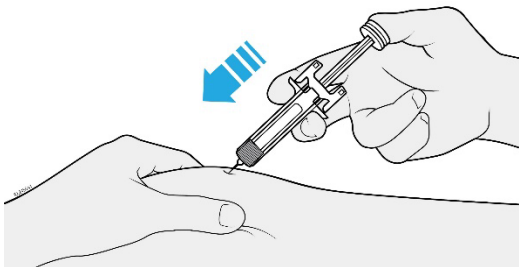
Important: Continue to pinch the skin until injection is complete.

4c. Insert the needle into the pinched skin.



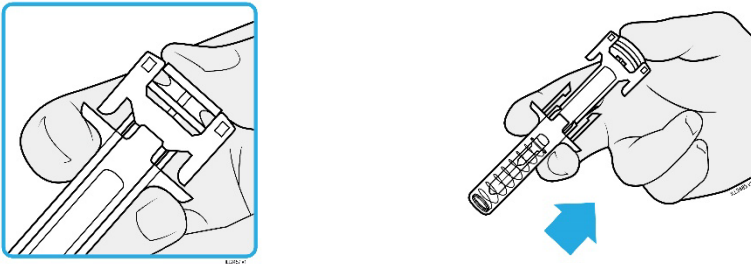
- Insert the needle into the pinched skin either straight in or at least a 45-degree angle.
- Do NOT place your finger on the plunger rod while inserting the needle, as this may result in lost medicine.

4d. Slowly press the plunger head down until it is completely between the needle guard clips.



- Do NOT pull back on the plunger at any time.
- Do NOT remove syringe until all medication is delivered.

4e. Keep pressure on the plunger head and remove needle from skin.



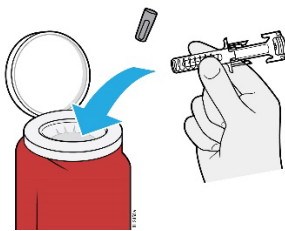
- Keep pressure on the plunger head and take the needle out of the skin.
- Let go of the skin after needle is removed.
- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is entirely covered by the needle guard.

If a second injection is required...

4f. Repeat steps 2a – 4e if a second injection is required.

- Check your prescription for your dose. If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes.
 - If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself a second injection right after the first.
- Repeat Steps 2a – 4e for the second injection using a new syringe. Choose a different site for the second injection.
- Disposing and finishing Wezlana

5a. Place the used syringe and needle cap in the sharps disposal container.



Important:

- Never put the needle cap back on.
- Do NOT reuse the syringe.
- Put the syringe in the sharps disposal container right away after use. Do NOT throw away (dispose of) loose syringes in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a rigid heavy-duty plastic,
- Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- Upright and stable during use,
- Leak-resistant, and
- Properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or provincial laws about how you should throw away syringes and needles.

Do NOT dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do NOT recycle the sharps disposal container.

If you have any question, talk to your healthcare professional.

5b. Check injection site.

- Do NOT rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if necessary.

INSTRUCTIONS FOR INJECTING Wezlana FROM a 45 mg / 0.5 mL VIAL

A. Important information you need to know before injecting Wezlana from a vial:

- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by your healthcare professional.
 - If your dose is 45 mg or less, you will receive one 45 mg vial.
 - If your dose is 90 mg, you will receive two 45 mg vials and you will need to give yourself two injections, one right after the other.
- Children 12 years of age and older weighing less than 60 kg require a dose lower than 45 mg.
- Check the expiration date on the vial and carton. If the expiration date has passed, do not use it. If the expiration date has passed, call your healthcare professional, or call 1-866-502-6436 for help.
- Check the vial for any particles or discolouration. Your vial should look clear and colourless to light yellow.
- Do NOT use if it is frozen, discoloured, cloudy or has large particles. Get a new vial.
- **Do NOT shake the vial at any time.** Shaking your vial may damage your Wezlana medicine. If your vial has been shaken, do not use it. Get a new vial.
- Vial can be stored at room temperature up to 30°C for up to 30 days in the original carton to protect from light.

- Do NOT use a Wezlana vial more than one time, even if there is medicine left in the vial. After the rubber stopper is punctured, Wezlana can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused Wezlana after you give your injection. Do NOT use the syringe if it has been frozen.
- Safely throw away (dispose of) Wezlana vials after use.
- Do NOT re-use syringes or needles. See Step 6: Dispose of the needles and syringes.
- To avoid needle-stick injuries, do NOT recap needles.

B. Gather supplies you will need to prepare Wezlana and to give your injection.

You will need:

- a syringe with the needle attached, you will need a prescription from your healthcare professional to get syringes with the needles attached from your pharmacy.
- alcohol wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of Wezlana
- sharps disposal container. See Step 6: Dispose of the needles and syringes.

Adhesive bandage



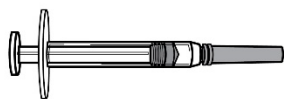
Alcohol wipes



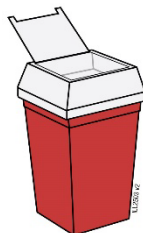
Cotton balls or gauze pads



Wezlana Vial



Syringe and attached needle



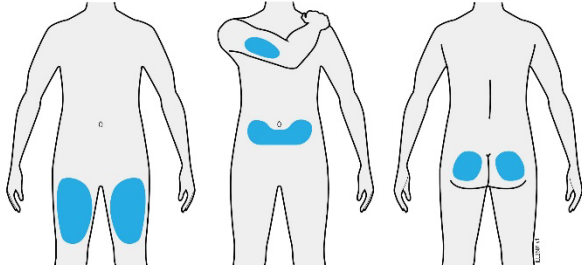
Sharps disposal container

Step 1: Prepare the injection

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.

Step 2: Prepare your injection site

- Choose an injection site around your stomach area (abdomen), buttocks, and upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used.



* Areas in blue are recommended injection sites.

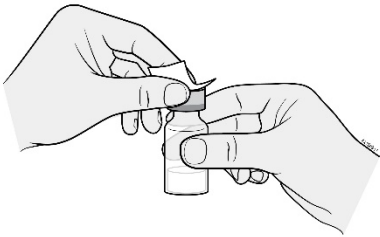
- **Use a different injection site for each injection.** Do NOT give an injection in an area of the skin that is tender, bruised, red or hard.
- Clean the skin with an alcohol wipe where you plan to give your injection.
- Do NOT touch this area again before giving the injection. Let your skin dry before injecting.
- Do NOT fan or blow on the clean area.

Step 3: Prepare the vial

- Remove the cap from the top of the vial. Throw away the cap but do not remove the stopper.



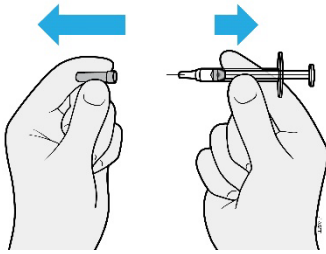
- Clean the rubber stopper with an alcohol wipe.



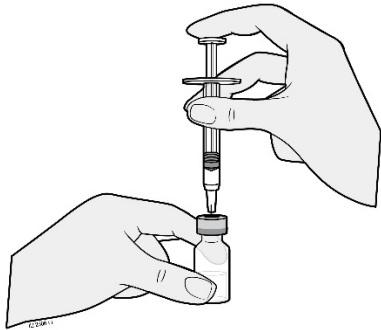
- Do NOT touch the rubber stopper after you clean it.
- Put the vial on a flat surface.

Step 4: Prepare the needle

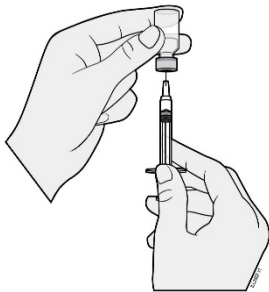
- Pick up the syringe with the needle attached.
- Remove the cap that covers the needle.



- Throw the needle cap away. Do NOT touch the needle or allow the needle to touch anything.
- Carefully pull back on the plunger to the line that matches the dose prescribed by your healthcare professional.
- Hold the vial between your thumb and index (pointer) finger.
- Use your other hand to push the needle through the centre of the rubber stopper.

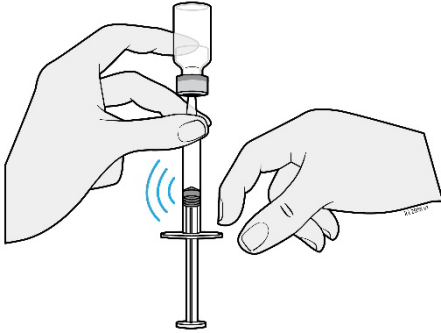


- Push down on the plunger until all of the air has gone from the syringe into the vial.
- Turn the vial and the syringe upside down.



- Hold the Wezlana vial with one hand.
- It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.
- Pull back on the syringe plunger with your other hand.
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose.
- **Do NOT remove the needle from the vial.** Hold the syringe with the needle pointing up to see if it has any air bubbles inside.

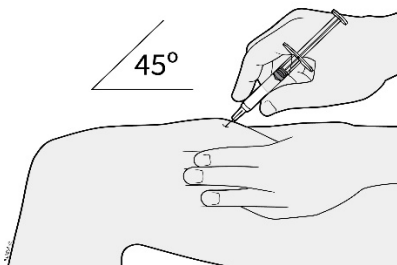
- If there are air bubbles, gently tap the side of the syringe until the air bubbles rise to the top.



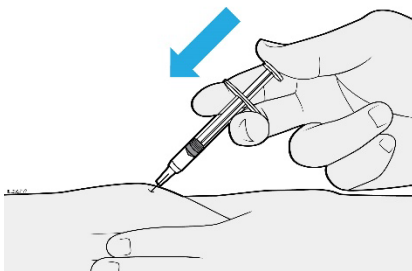
- Slowly press the plunger up until all of the air bubbles are out of the syringe (but none of the liquid is out).
- Remove the syringe from the vial. Do not lay the syringe down or allow the needle to touch anything.

Step 5. Inject Wezlana

- Hold the barrel of the syringe in one hand, between the thumb and index fingers.
- Do NOT pull back on the plunger at any time.
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle.



- 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 syringe is empty, pull the needle out of your skin and let go of the skin.

- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal.
- You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

If your dose is 90 mg, you will receive two 45 mg vials and you will need to give yourself a second injection right after the first. Repeat Steps 1 - 5 using a new syringe. Choose a different site for the second injection.

Step 6: Dispose of the needles and syringes

- Do NOT re-use a syringe or needle.
- To avoid needle-stick injuries, do not recap a needle.
- Put your needles and syringes in the sharps disposal container right away after use. Do NOT throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a sharps disposal container, you may use a household container that is:
 - Made of a rigid heavy-duty plastic,
 - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - Upright and stable during use,
 - Leak-resistant, and
 - Properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or provincial laws about how you should throw away syringes and needles.
- Do NOT dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.
- Do NOT recycle the sharps disposal container.
- Throw away the vial into the container where you put the syringes and needles.
- If you have any question, talk to your healthcare professional.

What are possible side effects from using Wezlana?

These are not all the possible side effects you may have when taking Wezlana. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects 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
- Sinus infection

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

Serious Infections

Ustekinumab 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 professional before you start using Wezlana. 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 professional right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.

Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Wezlana and during treatment with Wezlana.

Cancers

Ustekinumab may decrease the activity of your immune system and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Wezlana 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 healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Infected nose, sinuses or throat (cold)	X		
COMMON			
Sore throat, nasal congestion	X		
Allergic reaction (skin rash)		X	
UNCOMMON			
Cellulitis (skin infection)		X	
Vaginal yeast infections	X		
Tooth abscess / tooth infection		X	
RARE			
Serious allergic reactions (eg., swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction).			X
Increase in redness and shedding of skin.		X	

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 1,000.

In general, the side effects of ustekinumab seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store Wezlana vials and prefilled syringes in a refrigerator between 2°C - 8°C. Store Wezlana vials standing up straight.

Store Wezlana in the original carton to protect it from light until the time of use.

Do NOT freeze Wezlana. Do NOT shake Wezlana.

If needed, individual prefilled syringe and 45 mg vial may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe or 45 mg vial is first removed from the refrigerator on the carton. Once the prefilled syringe or the 45 mg vial has been stored at room temperature, it should not be returned to the refrigerator.

Discard the prefilled syringe or the 45 mg vial if not used within 30 days at room temperature storage. Do not use Wezlana after the expiration date on the carton or on the prefilled syringe or on the 45 mg vial.

Keep out of reach and sight of children.

If you want more information about Wezlana:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**WEZLANA**™ (pronounced *wez-LAHN-uh*)

ustekinumab injection

Solution for Subcutaneous Injection

Prefilled ConfiPen™ Autoinjector

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

Wezlana is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is Wezlana used for?

- **Adults with Plaque Psoriasis**

Wezlana is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

Wezlana is a prescription medicine that is approved for children and adolescent patients 6 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**

Wezlana 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 Wezlana 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 or ulcerative colitis**

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

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

Wezlana / Wezlana I.V. may help reduce or stop the use of your corticosteroid medication.

How does Wezlana work?

Wezlana 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, Crohn's disease or ulcerative colitis, 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.

What are the ingredients in Wezlana?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose. No preservatives are present.

Wezlana comes in the following dosage forms:

Prefilled Syringe:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Single-use Vial:

- 45 mg / 0.5 mL

Prefilled ConfiPen Autoinjector:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

Do not use Wezlana 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 Wezlana, Wezlana I.V., or any of the other ingredients in Wezlana (see What are the ingredients in Wezlana? section). You should not receive a live vaccine when taking Wezlana I.V.

If you used Wezlana I.V. while pregnant, tell your baby's healthcare professional about your Wezlana I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Wezlana. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Wezlana or Wezlana I.V. Ask your healthcare professional 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 healthcare professional 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, think you might be pregnant, planning to become pregnant, or breast-feeding. Ustekinumab may pass into your breast milk in small amounts.

Contact your healthcare professional 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).

There is limited experience with ustekinumab in pregnant and breast-feeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Wezlana and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breast-feeding your healthcare professional will help you decide whether or not to use Wezlana.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Wezlana:

- Wezlana may change the way the body responds to live vaccines. You should not receive a live vaccine while taking Wezlana.
- Wezlana may interact with other medications that decrease the activity of the immune system.

How to take Wezlana:

Wezlana may be injected by your healthcare professional. In children 6 to 17 years of age, it is recommended that all doses of Wezlana be administered by a healthcare professional. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject Wezlana under the skin (subcutaneously) yourself. Before you self-inject Wezlana, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare professional to schedule a training session. Call your healthcare professional if you have any questions about giving yourself an injection. Wezlana is not to be mixed with other liquids for injection.

Usual dose:**Psoriasis**

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

Adults:

The recommended dose of Wezlana is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional 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 (6 years of age or older):

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

Weight	Recommended dose of Wezlana	Dosage Form
< 60 kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Prefilled syringe, vial, prefilled ConfiPen autoinjector
> 100 kg	90 mg	Prefilled syringe, prefilled ConfiPen autoinjector

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL / kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of Wezlana for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25

Injection volumes of Wezlana for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48
59	44.3	0.49

In children 6 to 17 years of age with psoriasis, it is recommended that Wezlana be administered by a healthcare professional. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer Wezlana to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected.

Psoriatic Arthritis

For treatment of psoriatic arthritis, Wezlana is given by injection under the skin. The recommended dose of Wezlana 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 and ulcerative colitis

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

Weight	Recommended Dose of Wezlana 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 and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Wezlana I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Wezlana)
Further treatment	Every 8 weeks* Subcutaneous injection (Wezlana)

*Your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

The Entrust™ Patient Support Services facilitate the administration of Wezlana through the Entrust™ Infusion Network with clinics staffed by qualified healthcare professionals specially trained in the administration of Wezlana infusions. Information about the Entrust™ Patient Support Services can be obtained by calling 1-877-936-2735.

Overdose:

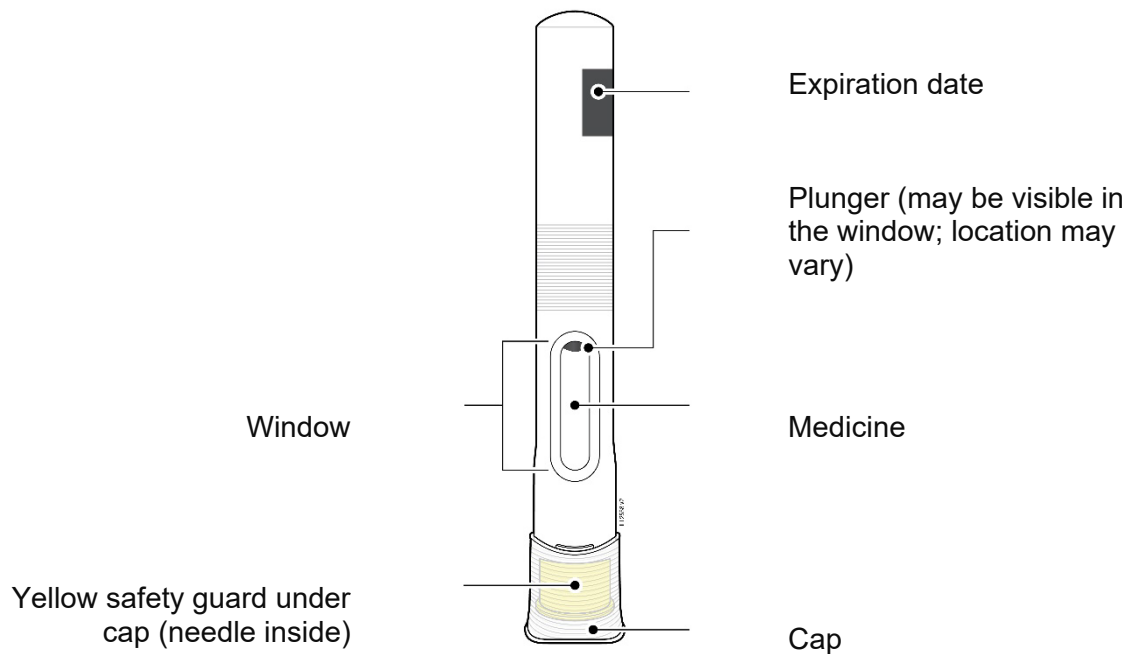
Call your healthcare professional if you accidentally inject Wezlana more frequently than instructed.

If you think you, or a person you are caring for, have taken too much Wezlana, contact a healthcare professional, 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 professional for guidance.

**INSTRUCTIONS FOR INJECTING Wezlana USING A PREFILLED AUTOINJECTOR:
Getting to know the prefilled autoinjector**



Important Information You Need to Know Before Injecting Wezlana

Dosing:

- Wezlana comes in two different doses: 45 mg and 90 mg. Check the prescription to make sure you have the correct dose.
- The label colour and window size of the autoinjector will be different for each dose. The amount of medicine in the autoinjector will also be different for each dose.



45 mg



90 mg

Important:

- If the dose is 90 mg, you will receive either one 90 mg autoinjector or two 45 mg autoinjectors.
 - If you receive two 45 mg autoinjectors for a 90 mg dose, you will need to give a second injection right after the first.
 - Repeat Steps 1-16 for the second injection using a new autoinjector.
 - Choose a different site for the second injection.

Using your Wezlana ConfiPen autoinjector:

- It is important that you do not try to give an injection until you have fully read and understood the Instructions for Use
- If your healthcare professional decides that you or a caregiver can give your Wezlana injection at home, you should receive training on the right way to prepare and inject Wezlana. Do not try to inject Wezlana yourself until you have been shown the right way to give the injections by your healthcare professional.
- Do NOT use the autoinjector if the carton is damaged or the seal is broken.
- Do NOT use the autoinjector after the expiration date on the label.
- Do NOT shake the autoinjector.
- Do NOT remove the cap from the autoinjector until you are ready to inject.
- Do NOT use the autoinjector if it has been frozen.
- Do NOT use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken, even if you cannot see the break. Use a new autoinjector, and call 1-866-502-6436.
- The autoinjector is not made with natural rubber latex.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children.

Storing and Preparing to Inject Wezlana

1. Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 2°C to 8°C.
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- Do NOT freeze the autoinjector.
- Do NOT store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector out of the sight and reach of children.

2. Wait 30 minutes for the autoinjector to reach room temperature.

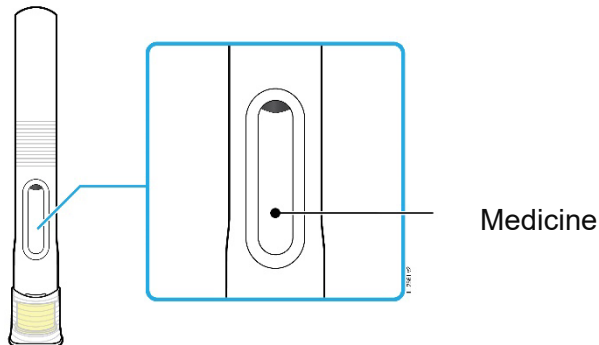
- Remove the number of autoinjectors you need for the injection from the refrigerator.
- Let the autoinjector warm up naturally.
- Do NOT heat the autoinjector with hot water, a microwave, or direct sunlight.
- Do NOT put the autoinjector back in the refrigerator once it reaches room temperature.
- Do NOT shake the autoinjector at any time.
- Using the autoinjector at room temperature ensures the full dose is delivered and allows for a more comfortable injection.

3. You may keep Wezlana at room temperature for up to 30 days, if needed.

- For example, when you are travelling, you may keep WEZLANA at room temperature.
- Keep it at room temperature up to 25°C.
- Do NOT use if the autoinjector has been stored above 30°C.
- Do NOT put back in refrigerator.
- Record the date you removed it from the refrigerator and use within 30 days.

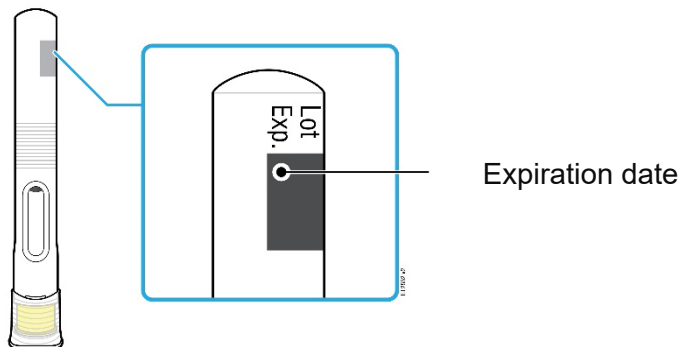
Important: Place the autoinjector in a sharps container if it has reached room temperature and has not been used within 30 days.

4. Inspect the medicine. It should be clear and colourless to pale yellow.



- It is okay to see bubbles.
- Do NOT use Wezlana if the medicine is cloudy, discoloured, or has particles.

5. Check the expiration date (Exp.) and inspect the autoinjector for damage.



- Do NOT use the autoinjector if the expiration date has passed.
- Do NOT use the autoinjector if:
 - the cap is missing or loose,
 - It has cracks or broken parts, or
 - It has been dropped on a hard surface.
- Make sure you have the right medicine and dose.

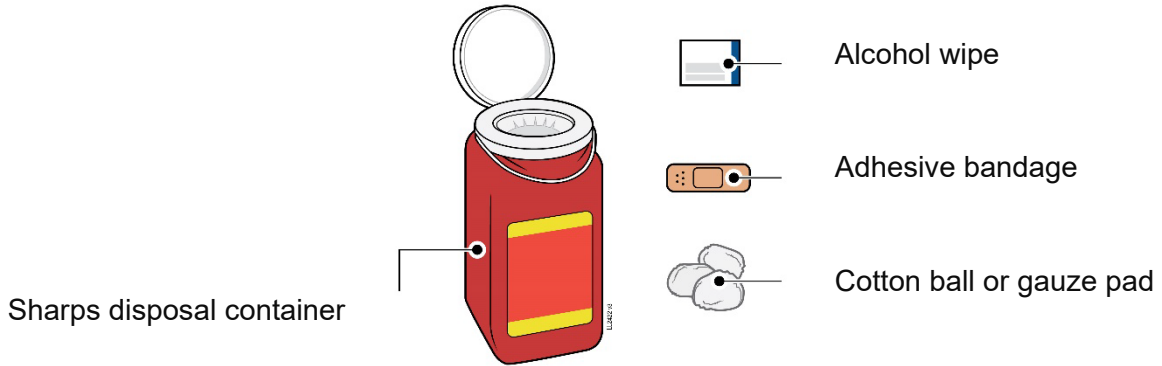
Important: If the medicine is cloudy, discoloured, or has particles, or if the autoinjector is damaged or expired, call 1-866-502-6436.

Getting Ready to Inject Wezlana

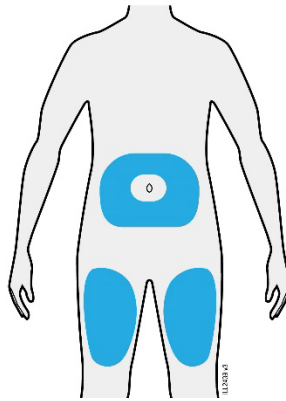
6. Gather and place the following items for the injection on a clean, flat, and well-lit surface:

- Wezlana autoinjector (room temperature),
- Sharps disposal container (see Disposing of Wezlana and Checking the Injection Site),

- Alcohol wipe,
- Adhesive bandage, and
- Cotton ball or gauze pad.



7. Select one (1) of these injection locations.



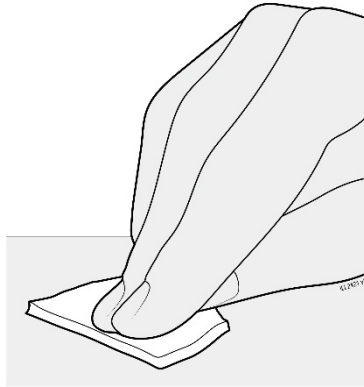
- Select the front of your thigh or stomach [except for the 5 cm (2 inch) area around your belly button].
- Someone else can inject in your thigh, stomach, back of the upper arm, or buttocks.

Important: Avoid areas with scars, stretch marks or where the skin is tender, bruised, red or hard.

8. Wash your hand thoroughly with soap and water.



9. Clean the injection site with an alcohol wipe.



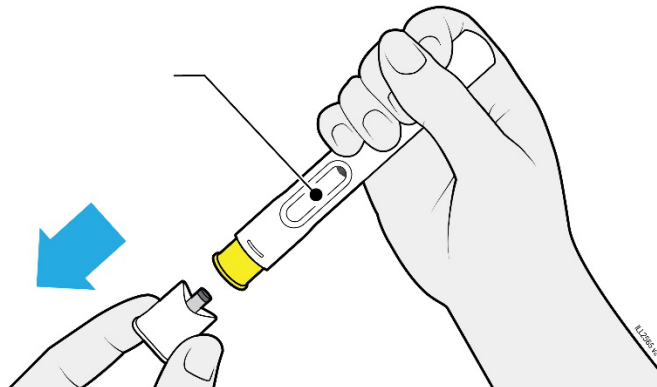
- Let the skin dry on its own.
- Do NOT touch this area again before injecting.

Injecting Wezlana

Important: Only remove the cap when you can inject right away (within 5 minutes) because the medicine can dry out. Do NOT recap.

10. Grasp the autoinjector so you can see the window. Pull hard to remove the cap. You may twist the cap to help remove it.

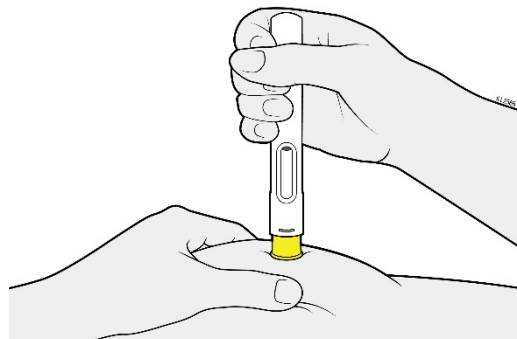
Window should be visible



- Never put the cap back on. It may damage the needle.
- It is normal to see a drop of medicine come out of the needle or yellow safety guard.

Important: Do NOT touch or push the yellow safety guard. Do NOT put your finger inside of the yellow safety guard.

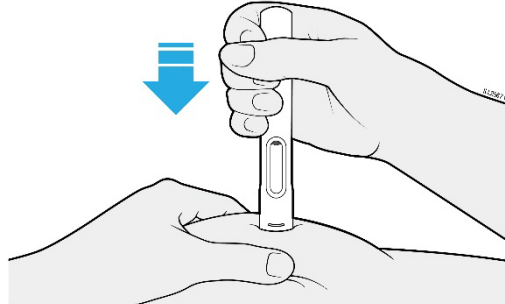
11. Pinch the skin to create a firm surface at the injection site. Place the yellow safety guard straight against the pinched skin.



- Keep the skin **pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90 degree angle).

12. Firmly push the autoinjector down until the yellow safety guard stops moving. Hold the autoinjector down, do NOT lift.

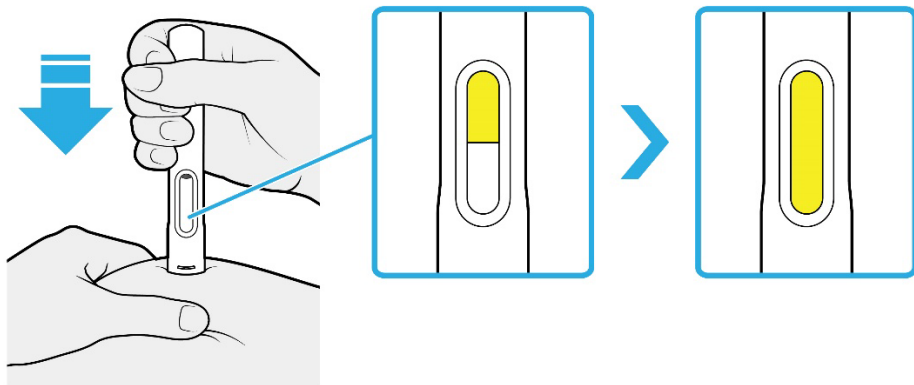
PUSH & HOLD
down to start injection



- The needle will insert and the injection begins.
- You may hear or feel a click.
- Hold the autoinjector straight and steady on the skin.

13. Keep pushing down the autoinjector. Wait for the window to turn fully yellow.

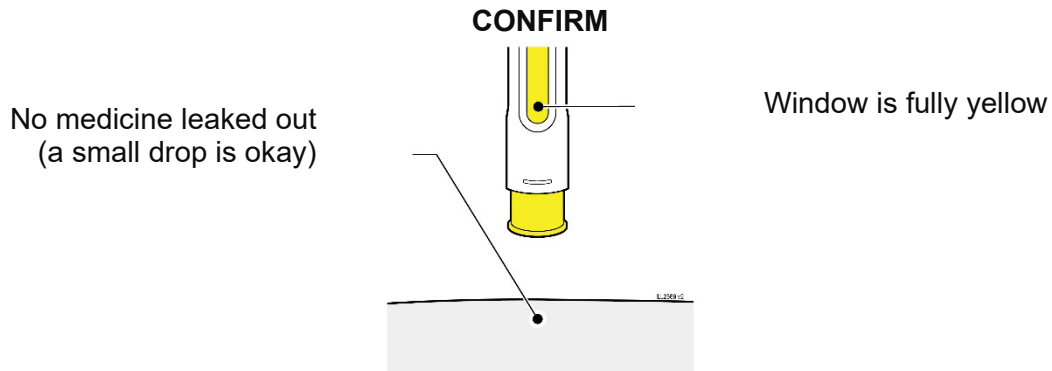
WATCH
window will turn fully yellow



- The injection can take up to 15 seconds to complete. You may hear or feel a click.
- After the window turns fully yellow, lift the autoinjector away from the skin.

Disposing of Wezlana and Checking the Injection Site

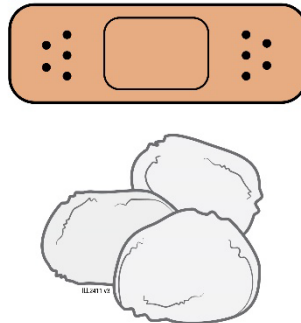
14. Confirm a full dose of medicine was injected.



- Do NOT touch the yellow safety guard.
- A small amount of liquid on the injection site is okay.

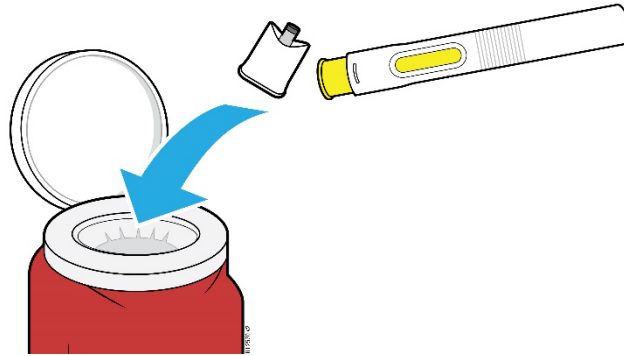
Important: If the window has not turned fully yellow, if it looks like the medicine is still coming out, or if you see several drops of medicine, a full dose was not injected. Call your healthcare professional immediately.

15. Check the injection site.



- Do NOT rub the injection site.
- If there is blood, press a cotton ball or gauze pad on the injection site.
- Apply an adhesive bandage if necessary.

16. Place the used autoinjector and cap in a sharps disposal container.



Important: Do not throw away the autoinjector in your household trash.

- Do NOT reuse the autoinjector
- Do NOT touch the yellow safety guard.

Additional information about your sharps disposal container:

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- Leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

Disposing of sharps containers:

- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local or provincial laws about how you should throw away syringes and needles.
- Do NOT dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.
- Do NOT recycle the sharps disposal container.
- If you have any questions, talk to your healthcare professional.

What are possible side effects from using Wezlana?

These are not all the possible side effects you may have when taking Wezlana. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects 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
- Sinus infection

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

Serious Infections

Ustekinumab 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 professional before you start using Wezlana. 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 professional right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.

Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Wezlana and during treatment with Wezlana.

Cancers

Ustekinumab may decrease the activity of your immune system and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving Wezlana 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 healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Infected nose, sinuses or throat (cold)	X		
COMMON			
Sore throat, nasal congestion	X		
Allergic reaction (skin rash)		X	
UNCOMMON			
Cellulitis (skin infection)		X	
Vaginal yeast infections	X		
Tooth abscess / tooth infection		X	
RARE			
Serious allergic reactions (eg., swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction).			X
Increase in redness and shedding of skin.		X	

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 1,000.

In general, the side effects of ustekinumab seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store Wezlana prefilled ConfiPen autoinjectors in a refrigerator between 2°C to 8°C.

Store Wezlana in the original carton to protect it from light until the time of use.

Do NOT freeze Wezlana. Do NOT shake Wezlana.

If needed, prefilled ConfiPen autoinjectors may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled ConfiPen autoinjector is first removed from the refrigerator on the carton. Once the prefilled ConfiPen autoinjector has been stored at room temperature, it should not be returned to the refrigerator.

Discard the prefilled ConfiPen autoinjector if not used within 30 days at room temperature storage. Do not use Wezlana after the expiration date on the carton or on the prefilled ConfiPen autoinjector.

Keep out of reach and sight of children.

If you want more information about Wezlana:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.amgen.ca, or by calling 1-866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **WEZLANA™ I.V.** (pronounced *wez-LAHN-uh*)

ustekinumab for injection

Solution for Intravenous Infusion

Read this carefully before you start taking **Wezlana I.V.** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Wezlana I.V.**

Wezlana I.V. is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA® I.V. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is Wezlana I.V. used for?

Adults with Crohn's disease or ulcerative colitis

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

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

How does Wezlana I.V. work?

Wezlana 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 and ulcerative colitis, 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.

What are the ingredients in Wezlana I.V.?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: EDTA disodium salt dihydrate, L-histidine, L-histidine hydrochloride monohydrate, L-methionine, Polysorbate 80, and sucrose. No preservatives are present.

Wezlana I.V. comes in the following dosage forms:

Single-use Vial:

- 130 mg / 26 mL

Do not use Wezlana 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 Wezlana I.V. or Wezlana or any of the other ingredients in Wezlana I.V. (see [What are the ingredients in Wezlana I.V.](#) for a complete list of ingredients).

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

If you used Wezlana I.V. while pregnant, tell your baby's healthcare professional about your Wezlana I.V. use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Wezlana I.V. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to Wezlana I.V. or Wezlana. Ask your healthcare professional 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 healthcare professional 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, think you might be pregnant, planning to become pregnant, or breastfeeding. Ustekinumab may pass into your breast milk in small amounts.

Contact your healthcare professional 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).

There is limited experience with ustekinumab in pregnant and breast-feeding women. If you are a woman of childbearing potential, you should use effective contraception when starting Wezlana I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breast-feeding, your healthcare professional will help you decide whether or not to use Wezlana I.V./Wezlana.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Wezlana I.V.:

- Wezlana I.V. may change the way the body responds to live vaccines. You should not receive a live vaccine while taking Wezlana I.V.
- Wezlana I.V. may interact with other medications that decrease the activity of the immune system.

How to take Wezlana I.V.:

Crohn's disease and ulcerative colitis

Usual dose:

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

Weight	Recommended Dose of Wezlana 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 and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (Wezlana I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (Wezlana)
Further treatment	Every 8 weeks* Subcutaneous injection (Wezlana)

* Your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

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

The Entrust™ Patient Support Services facilitate the administration of Wezlana through the Entrust™ Infusion Network with clinics staffed by qualified healthcare professionals specially trained in the administration of Wezlana infusions. Information about the Entrust™ Patient Support Services can be obtained by calling 1-877-936-2735.

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.

If you think you, or a person you are caring for, have taken too much Wezlana I.V. / Wezlana, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

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These are not all the possible side effects you may have when taking Wezlana I.V. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects 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
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infections such as chest infections, or skin infections or shingles that could have serious complications.

Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Wezlana I.V.

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Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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COMMON			
Sore throat, nasal congestion	X		
Allergic reaction (skin rash)		X	
UNCOMMON			
Cellulitis (skin infection)		X	
Vaginal yeast infections	X		
Tooth abscess / tooth infection		X	
RARE			
Serious allergic reactions (eg., swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction).			X
Increase in redness and shedding of skin.		X	

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enough to interfere with your daily activities, tell your healthcare professional.

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- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store Wezlana I.V. vials in a refrigerator between 2°C – 8°C. Store Wezlana I.V. vials standing up straight.

Store Wezlana I.V. in the original carton to protect it from light until the time of use.

Do NOT freeze Wezlana I.V. Do NOT shake Wezlana I.V.

Keep out of reach and sight of children.

If you want more information about Wezlana I.V.:

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This leaflet was prepared by: Amgen Canada Inc.

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