# WEZLANA®

## Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

## 1. Why am I using WEZLANA?

WEZLANA contains the active ingredient ustekinumab. WEZLANA is used to treat adults and children with plaque psoriasis, and adults with psoriatic arthritis, Crohn's disease, or ulcerative colitis.

For more information, see Section 1. Why am I using WEZLANA? in the full CMI.

## 2. What should I know before I use WEZLANA?

Do not use if you have ever had an allergic reaction to WEZLANA or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section 2. What should I know before I use WEZLANA? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with WEZLANA and affect how it works.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

## 4. How do I use WEZLANA?

- Your doctor will determine the correct dose of WEZLANA for you and how often you should receive it.
- WEZLANA can be administered by an injection under the skin. It can also be injected into a vein by a doctor or nurse.

More instructions can be found in Section 4. How do I use WEZLANA? in the full CMI.

## 5. What should I know while using WEZLANA?

| | |
|---|---|
| **Things you should do** | • Remind any doctor, dentist or pharmacist you visit that you are using WEZLANA.<br>• Tell your doctor about your medical conditions before each treatment.<br>• Tell your doctor if you become pregnant while using WEZLANA. |
| **Things you should not do** | • You should not receive a live vaccine while taking WEZLANA.<br>• Do not use WEZLANA to treat any other complaint unless your doctor says so.<br>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. |
| **Looking after your medicine** | • Keep WEZLANA in a refrigerator between (2°C and 8°C). Do not freeze.<br>• Do not shake.<br>• Keep WEZLANA in the pack to protect from light until it is time to use it. |

For more information, see Section 5. What should I know while using WEZLANA? in the full CMI.

## 6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of WEZLANA include cold symptoms, dizziness, headache, sore throat, diarrhoea, nausea, vomiting, itching, back, muscle or joint pain, injection site pain or redness, tiredness and sinus. WEZLANA may cause serious allergic reactions.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking WEZLANA**

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

# WEZLANA®

**Active ingredient(s):** Ustekinumab

## Consumer Medicine Information (CMI)

This leaflet provides important information about using WEZLANA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using WEZLANA.**

**Where to find information in this leaflet:**


1. Why am I using WEZLANA?
2. What should I know before I use WEZLANA?
3. What if I am taking other medicines?
4. How do I use WEZLANA?
5. What should I know while using WEZLANA?
6. Are there any side effects?
7. Product details
8. Instructions for Use: WEZLANA 45 mg vial
9. Instructions for Use: WEZLANA 45 mg and 90 mg pre-filled syringe


## 1. Why am I using WEZLANA?

**WEZLANA contains the active ingredient ustekinumab, a monoclonal antibody.**

Monoclonal antibodies are proteins that recognise and bind to other unique proteins. Ustekinumab blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). IL-12 and IL-23 are made by your body's immune system. In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body. Ustekinumab can block IL-12 and IL-23 from causing the immune system to attack.

**WEZLANA is used to treat:**

- adults and paediatric patients (children and adolescents) 6 years and older with moderate to severe plaque psoriasis that is chronic (doesn't go away),
- adults with active psoriatic arthritis, an inflammatory disease of the joints that is usually accompanied by psoriasis,
- adults with moderately to severely active Crohn's disease, an inflammatory disease of the bowel.
- adults with moderate to severe ulcerative colitis, an inflammatory disease of the bowel.

## 2. What should I know before I use WEZLANA?

### Warnings

### Do not use WEZLANA if:

- you are allergic to ustekinumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

### Check with your doctor if you:

- 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 had TB (tuberculosis), or if you have recently been near anyone who might have TB. Your doctor will examine you for 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 WEZLANA and during treatment with WEZLANA,
- have or have had any type of cancer,
- have any new or changing lesions within psoriasis areas or on normal skin,
- have recently received or are scheduled to receive a vaccine. Patients receiving WEZLANA should not receive live vaccines. 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 problem,
- are receiving allergy immunotherapy,
- are pregnant, planning to become pregnant, or breastfeeding,
- have any other medical conditions,
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

### Pregnancy

Check with your doctor if you are pregnant or intend to become pregnant. Adequate contraception should be used to avoid falling pregnant. WEZLANA should only be used during a pregnancy if needed.

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

### Breastfeeding

Talk to your doctor if you are breastfeeding or intend to breastfeed. WEZLANA may pass into your breastmilk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use WEZLANA as it might be excreted in breast milk.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should not receive a live vaccine while taking WEZLANA. If you used WEZLANA while pregnant, tell your baby's doctor about your WEZLANA use before the baby receives any vaccines, including live vaccines, such as BCG vaccines (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect WEZLANA.**

## 4. How do I use WEZLANA?

### How is WEZLANA given

For the treatment of psoriasis or psoriatic arthritis WEZLANA is given by injection just under the skin (subcutaneously).

For the treatment of Crohn's Disease and ulcerative colitis, the first dose of WEZLANA will be given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. After this starting dose, all future doses of WEZLANA are given by injection just under the skin (subcutaneously).

All WEZLANA injections are for single use in one patient only.

WEZLANA is intended for use under the guidance and supervision of your doctor. In children and adolescents 6 years and older with psoriasis, it is recommended that WEZLANA be administered by a health care provider. When you start treatment, WEZLANA may be injected by your healthcare provider. If your doctor determines that it is appropriate, you or your caregiver may be able to administer it under the skin yourself if you wish, after proper training in injection technique.

It is important to remember that the first dose of WEZLANA for the treatment of Crohn's Disease or ulcerative colitis (intravenous infusion) will always be administered by your healthcare provider.

### How much and when to use

Your doctor will determine the correct dose of WEZLANA for you and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

For children and adolescents aged 6 years or older with psoriasis:

- The doctor will work out the right dose for you, including the amount (volume) of WEZLANA to be injected to give the right dose. The right dose for you will depend on your body weight at the time each dose is given. If you weigh less than 60 kg, the recommended dose is 0.75 mg of WEZLANA per kg body weight.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg WEZLANA.
- If you weigh more than 100 kg, the recommended dose is 90 mg WEZLANA.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

### How to use WEZLANA

Your first WEZLANA injection may be administered by your healthcare provider. In children and adolescents 6 years and older, it is recommended that all doses of WEZLANA be administered by a healthcare provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject WEZLANA under the skin (subcutaneously) yourself.

If you would like to self-inject WEZLANA under your skin, you or your caregiver must be trained by a healthcare professional to prepare an injection and give it to yourself. 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. WEZLANA is given alone and not mixed with other liquids for injection.

**WEZLANA should not be used:**

- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discoloured, cloudy or you can see other particulate matter floating in it;
- if you know, or think that it may have been exposed to extreme temperatures (such as being accidentally frozen or heated);
- with other liquids for injection.

### How to inject WEZLANA under the skin (subcutaneously)

It is important that you or your caregiver do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.

WEZLANA is available in a pre-filled syringe and a vial.

See the detailed “Instructions for Use” linked below and provided at the end of the CMI for instructions about the right way to store, prepare and give your WEZLANA injections at home:

- Vial instructions for use.
- Pre-filled syringe instructions for use.

### If you forget to use WEZLANA

If you miss your dose, inject the dose as soon as you remember, then talk to your doctor to discuss when you

should inject your next dose, and continue to use it as you would normally.

**Do not take a double dose to make up for the dose you missed.**

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

### If you use too much WEZLANA

If you think that you have used too much WEZLANA, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using WEZLANA?

### Things you should do

Always follow your doctor's instructions carefully.

Tell your doctor about your medical conditions before each treatment.

Tell your doctor if you become pregnant while using WEZLANA.

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

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using WEZLANA.

Remind any doctor, dentist, nurse or pharmacist you visit that you are using WEZLANA.

### Call your doctor straight away if you:

- If you develop headache, vision problems, seizures or change in mental status (for example confusion), tell your doctor immediately.
- If you develop fever or chills, itchiness or hives, chest pain, low or high blood pressure during, or within 3 days after, the infusion. These may be signs of an infusion-related reaction. You may need other medicines, or the infusion may need to be slowed down or stopped.

### Things you should not do

- You should not receive a live vaccine while taking WEZLANA.
- Do not use WEZLANA to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use WEZLANA:

- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discoloured, cloudy or you can see other particulate matter floating in it;
- if you know, or think that it may have been exposed to extreme temperatures (such as being accidentally frozen or heated).

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how WEZLANA affects you.

### Drinking alcohol

**Tell your doctor if you drink alcohol.** Alcohol did not impact the way WEZLANA works.

### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

- Keep WEZLANA in a refrigerator between (2℃ and 8℃).
- Do not freeze.
- Keep WEZLANA in the pack to protect from light until it is time to use it.
- Do not shake. Prolonged vigorous shaking may damage the product. If WEZLANA has been shaken vigorously, don't use it.

If needed, you may store WEZLANA pre-filled syringes or 45 mg vials at room temperature up to 30℃ for one period of up to 30 days.

- Write the date on the carton, when removed from the refrigerator.
- Once WEZLANA has been stored at room temperature, do not put it back in the refrigerator.
- Throw away WEZLANA if it has been kept for 30 days and has not been used or reached its original expiry.
- Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it in the bathroom or near a sink, or in the car or on windowsills.

**Keep it where young children cannot reach it.**

### Needle Disposal

After injection, used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your state or local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in regular rubbish.

### When to discard your medicine

Throw away WEZLANA if it has been kept for 30 days at room temperature and has not been used or reached its original expiry.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

WEZLANA is a medicine that may decrease the activity of your immune system and can increase your chances of getting serious side effects.

In general, the side effects of WEZLANA in children and adolescents 6 years and older are similar to those in adults. Ask your doctor or pharmacist to answer any questions you may have.

### Less serious side effects

| Less serious side effects | What to do |
|---|---|
| **Gut and digestion:**<br>• diarrhoea<br>• nausea, vomiting<br>• dental infections or sores in your mouth<br>**Lungs and Upper airway:**<br>• upper respiratory infections such as sinus and colds<br>• Sore throat<br>• Blocked or stuffy nose<br>**Injection site:**<br>• pain or redness<br>• bleeding, bruising, hardness, swelling and itch<br>**Skin:**<br>• acne<br>• painful rash, blisters<br>• eczema<br>• itching (pruritus)<br>• cellulitis<br>• shedding or peeling of the skin<br>• A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

| Less serious side effects continued | What to do |
|---|---|
| **Other:**<br>• tiredness, fatigue<br>• dizziness, headaches<br>• back, joint or muscle pain<br>• vaginal yeast (fungal) infection<br>• feeling weak | **Speak to your doctor if you have any of these less serious side effects and they worry you.** |

### Serious side effects

| Serious side effects | What to do |
|---|---|
| **Allergic reaction:**<br>• shortness of breath<br>• wheezing or difficulty breathing<br>• swelling of the face, lips, tongue or other parts of the body<br>**Infusion related reaction:**<br>• fever or chills<br>• rash, itching or hives on the skin<br>• chest pain<br>• change in blood pressure<br>**Other:**<br>• depression<br>• bronchitis or pneumonia | **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** |

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What WEZLANA contains

**WEZLANA 45 mg or 90 mg solution for injection for subcutaneous administration**

| | |
|---|---|
| **Active ingredient (main ingredient)** | ustekinumab |
| **Other ingredients (inactive ingredients)** | histidine/histidine hydrochloride monohydrate<br>polysorbate 80<br>sucrose<br>water for injections |

No preservatives are present.

**WEZLANA 130 mg concentrated solution for intravenous infusion**

| | |
|---|---|
| **Active ingredient (main ingredient)** | ustekinumab |
| **Other ingredients (inactive ingredients)** | disodium edetate<br>histidine<br>histidine hydrochloride monohydrate<br>methionine<br>polysorbate 80<br>sucrose<br>water for injections |

No preservatives are present.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What WEZLANA looks like

WEZLANA is a clear to opalescent, colourless to light yellow, sterile solution containing:

- ustekinumab 45 mg in 0.5 mL solution in a vial (for subcutaneous use) (AUST R 403012)
- ustekinumab 45 mg in 0.5 mL solution in a pre-filled syringe (for subcutaneous use) (AUST R 403013)
- ustekinumab 90 mg in 1.0 mL solution in a pre-filled syringe (for subcutaneous use) (AUST R 403011).
- ustekinumab 130 mg in 26 mL concentrated solution in a vial (for intravenous infusion only) (AUST R 403014)

The vials and pre-filled syringes are not made with natural rubber latex.

Vials and pre-filled syringes are available in packs containing:

- 1 vial, or
- 1 pre-filled syringe.

### Who distributes WEZLANA

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

This leaflet was prepared in August 2026.

## 8. Instructions for Use: WEZLANA 45 mg vial

**Before you use WEZLANA 45 mg vial, read this important information:**

Your doctor or nurse should show you how to prepare, measure your dose and give your injection of WEZLANA the right way.

It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.

WEZLANA is given as an injection:

- Ask your doctor or nurse to help you, or
- Ask someone who has been trained by a doctor or nurse to give your injections.

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 doctor.

- If your dose is 45 mg or less, you will receive one 45 mg vial.
- Children and adolescents 6 years of age or older who weigh less than 60kg may need to inject less than 0.5 mL.
- 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**.
- Your healthcare provider will recommend how much you need to inject.

Check the expiry date on the vial and carton**. Do not use** the WEZLANA vial after the expiry date.

Check the vial for any particles or discolouration. Your vial should look clear to opalescent and colourless to light yellow.

The WEZLANA vial should be stored in the refrigerator (2°C to 8°C). The 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 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.

**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, safely throw away any unused WEZLANA after you give your injection.

**Do not** re-use syringes or needles.

To avoid needle-stick injuries, **do not** recap needles.

Call your doctor or healthcare provider if you have any questions.

**Step 1: Gather all materials needed for your injection.**

Wash your hands thoroughly with soap and water and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included).

Place the following on a clean, well-lit work surface:

- a syringe with the needle attached, you will need a prescription from your healthcare provider to get syringes with the needles attached from your pharmacy
- alcohol wipes
- cotton ball or gauze pad
- adhesive bandage
- your prescribed dose of WEZLANA
- sharps disposal container

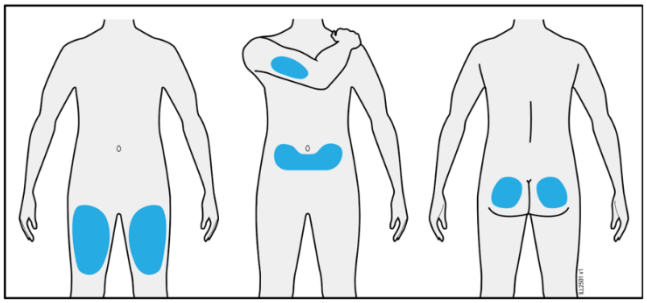
For a more comfortable injection, leave the vial at room temperature for about 30 minutes before injecting.

- **Do not** try to warm the vial by using a heat source such as hot water or microwave
- **Do not** leave the vial exposed to direct sunlight
- **Do not** shake the vial
- Keep the syringe with the needle out of the sight and reach of children

**Step 2: Prepare and clean your injection site.**

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

Use a different injection site for each injection.



Areas in blue are recommended injection sites

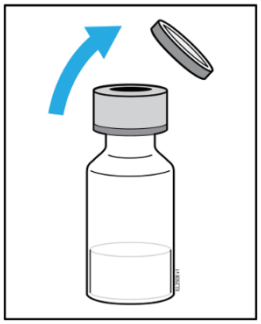
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- **Avoid** the area 5 cm around the belly button (navel).
- **Avoid**, if possible, skin involved with psoriasis.

Clean the skin with an alcohol wipe where you plan to give your injection.

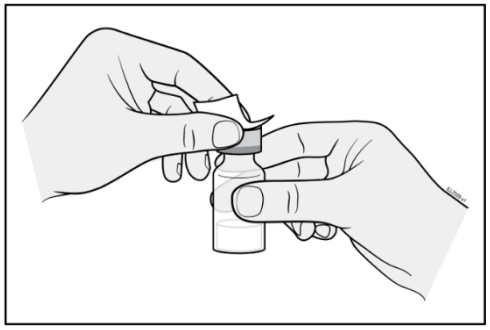
- Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.
- **Do not** touch this area again before giving the injection.

**Step 3: Prepare the vial.**

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



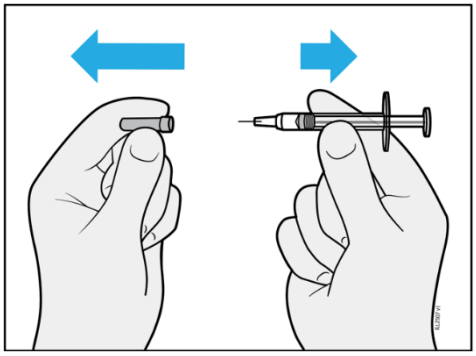
- Clean the rubber stopper with an alcohol wipe. Put the vial on a flat surface.



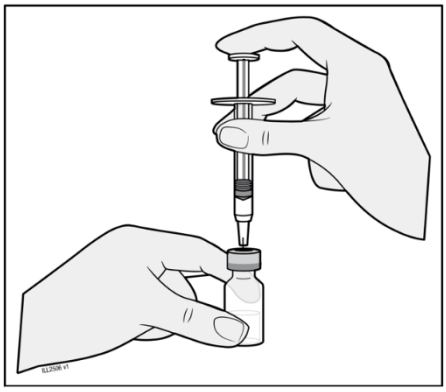
- **Do not** touch the rubber stopper after you clean it.

**Step 4: Prepare the syringe.**

- 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 doctor.
- Hold the vial between your thumb and index (pointer) finger.
- Use your other hand to push the syringe 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.

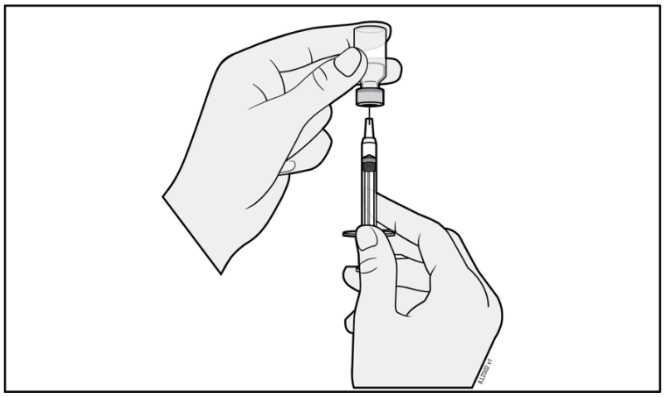


- Turn the vial and the syringe upside down.
- Hold the WEZLANA vial with one hand.

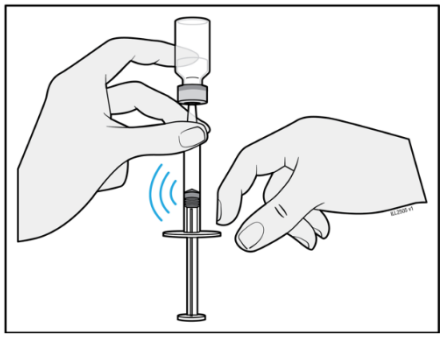
**Important:** It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.

- 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.

For children and adolescents 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your healthcare provider may be less than 0.5 mL. Your healthcare provider will advise how much liquid is needed to be drawn up.



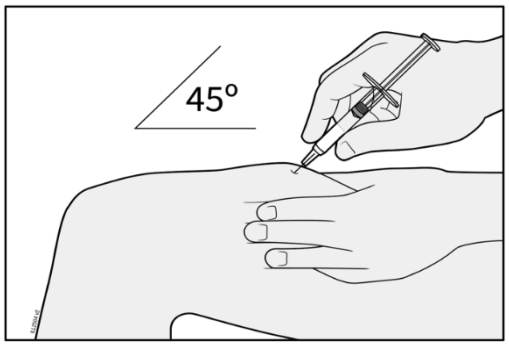
- **Do not** remove the needle from the vial.
- Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
- If there are air bubbles, gently tap the side of the syringe until the air bubbles rise to the top.
- Slowly press the plunger up until all of the air bubbles are out of the syringe (but none of the liquid is out). Remove the needle from the vial.



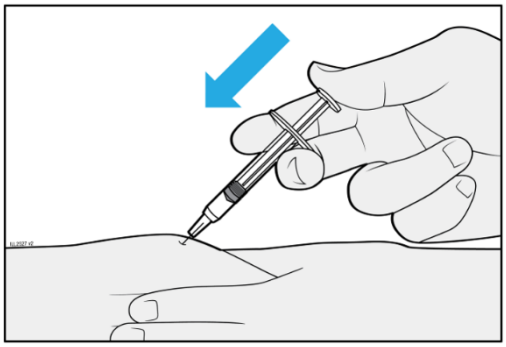
- **Do not** lay the syringe down or allow the needle to touch anything.

### 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 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. Immediately dispose of the empty syringe into the sharps container.
- 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 to 5 using a new syringe and vial.** Choose a different site for the second injection.

### Step 6: After the injection.

Discard the used vial and other supplies in a sharps disposal container.

Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

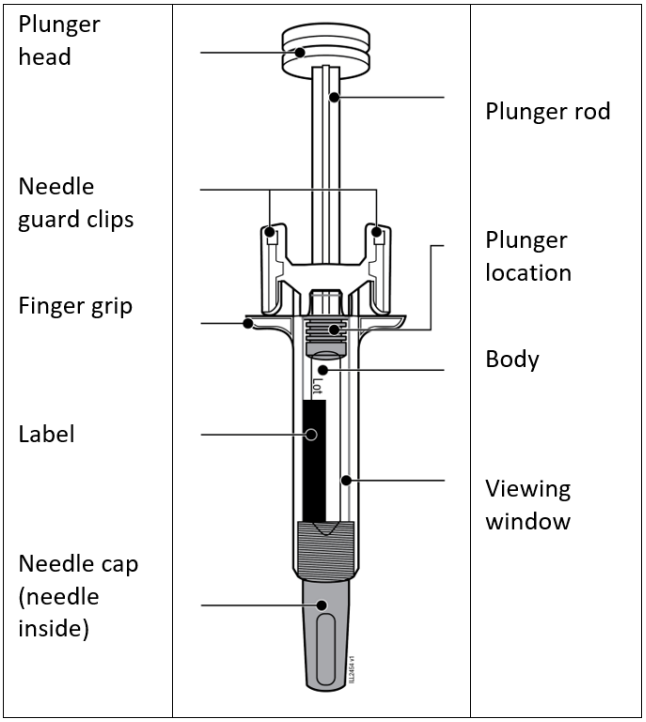
- **Do not** reuse a syringe or needle.
- To avoid needle-stick injuries, **do not** recap a needle.
- **Do not recycle syringes or throw them into household waste.**

**Please contact your health professional if you have any questions about WEZLANA**

## 9. Instructions for Use: WEZLANA 45 mg and 90 mg pre-filled syringe

**Before you use WEZLANA pre-filled syringe, read this important information:**

**Guide to parts**

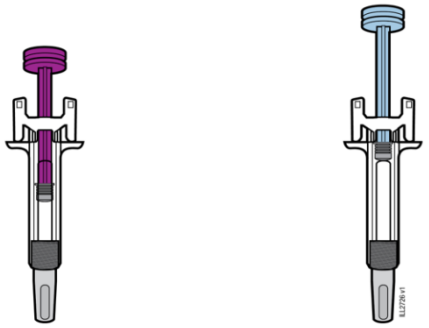



**Dosing:**

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 pre-filled syringe will be different for each dose. The amount of medicine in the syringe will also be different for each dose.

For example, it's 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/1.0mL**

Keep the WEZLANA pre-filled syringe in original carton to protect from light.

The WEZLANA pre-filled syringe should be stored in the refrigerator (2°C to 8°C).

You may keep the WEZLANA pre-filled syringe at room temperature up to 30°C for 30 days if needed, for example when you are travelling.

- Record the date you removed it from the refrigerator and use within 30 days.
- 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 the refrigerator.

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

It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.

WEZLANA is given as an injection into the tissue just under the skin (subcutaneous injection).

The WEZLANA pre-filled syringe is not made with natural rubber latex.

- **Do not** use the syringe if the carton is damaged or seal is broken.
- **Do not** freeze or use the WEZLANA pre-filled syringe if it has been frozen.
- **Do not** remove the grey needle cap from the pre-filled syringe until you are ready to inject.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.
- **Do not** attempt to activate the pre-filled syringe prior to injection.
- **Do not** attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe.
- **Do not** use the WEZLANA pre-filled syringe after the expiry date.

Call your doctor or healthcare provider if you have any questions.

**Step 1: Prepare.**

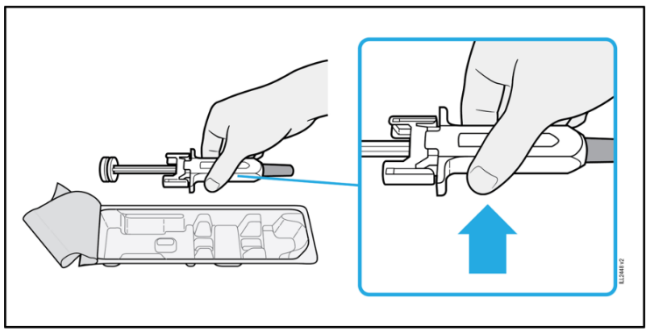
Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included).

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting. Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

- **Do not** try to warm the syringe by using a heat source such as hot water or microwave
- **Do not** leave the pre-filled syringe exposed to direct sunlight
- **Do not** shake the pre-filled syringe
- Keep pre-filled syringes out of the sight and reach of children

Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from tray.

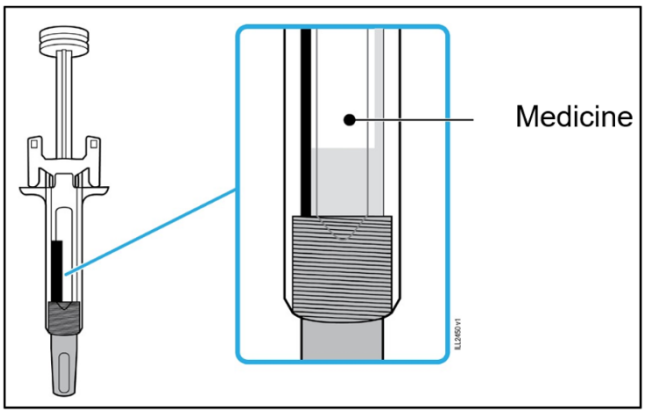


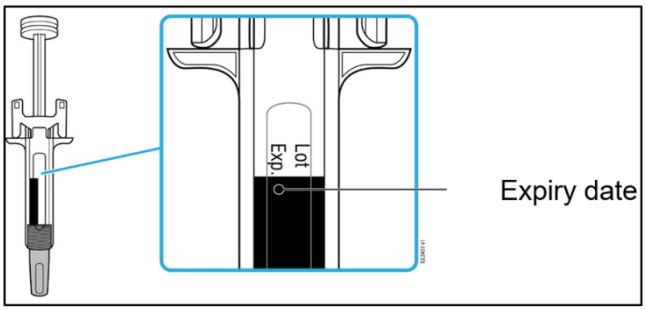
**Grab here**

For safety reasons:

- **Do not** grasp the plunger
- **Do not** grasp the grey needle cap

Inspect the medicine and pre-filled syringe, check the expiry date (EXP) on the label. It is okay to see air bubbles.




**Do not** use the pre-filled syringe if:

- The medicine is cloudy or there are particles in it. It must be a clear to opalescent, colourless to slightly yellow solution.
- Any part appears cracked or broken.
- The grey needle cap is missing or not securely attached.
- The expiry date has passed.
- It has been dropped on a hard surface.

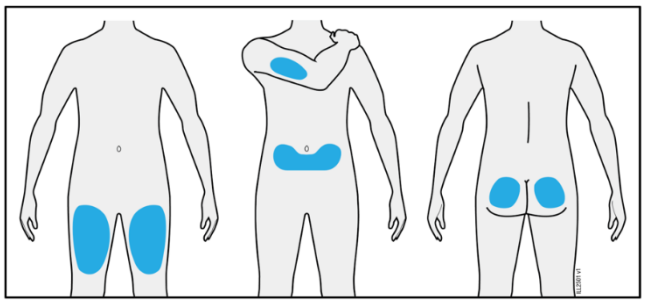
In all cases, call your doctor or healthcare provider.

**Step 2: Get ready for Your Injection.**

Wash hands thoroughly. Choose, prepare, and clean your injection site.

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

Use a different injection site for each injection.



Areas in blue are recommended injection sites

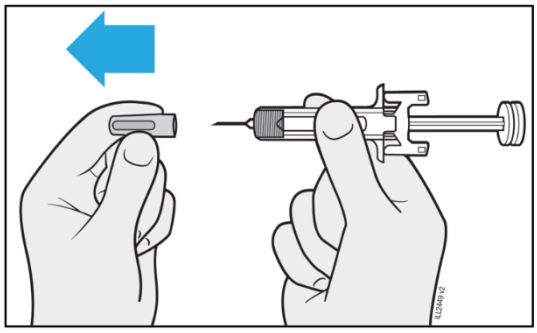
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- **Avoid** the area 5 cm around the belly button (navel).
- **Avoid**, if possible, skin involved with psoriasis.

Clean the skin with an alcohol wipe where you plan to give your injection.

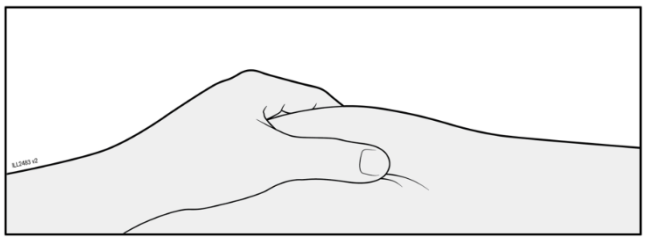
- Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.
- **Do not** touch this area again before giving the injection.

Carefully pull the grey needle cap straight out and away from your body.

- 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.
- **Do not** try to push air bubbles out. It is okay to see air bubbles.
- **Do not** let anything touch the needle after the cap is removed.



Pinch the skin firmly between your thumb and fingers, creating an area of about two inches (5 cm) wide.

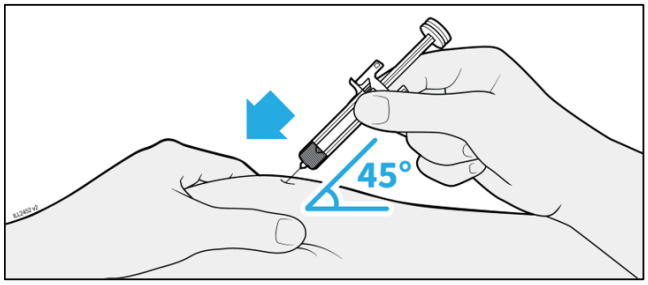


*It is important to keep the skin pinched when injecting.*

**Step 3: Inject WEZLANA**

*Hold the pinch. INSERT the needle into the pinched skin at a 45 degree angle.*

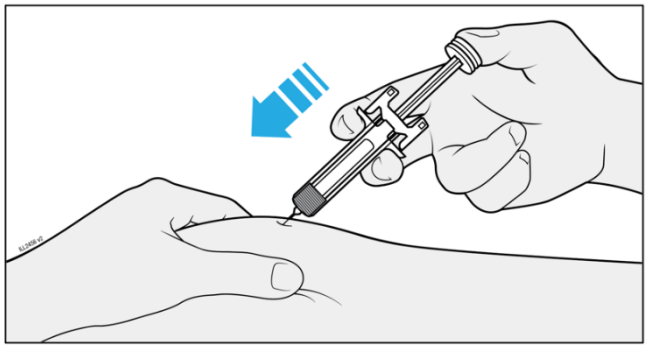
**INSERT**




- **Do not** touch the cleaned area of the skin
- **Do not** place your finger on the plunger rod while inserting the needle, as this may result in lost medicine.

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

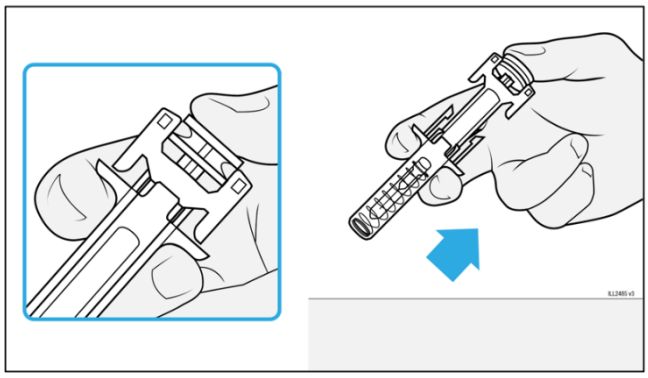
**INJECT**



- **Do not** pull back on the plunger at any time.
- **Do not** remove syringe until all medicine has been injected.

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

**LIFT**



Keep pressure on the plunger head and take the needle out of the skin.

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.

- **Do not** put the grey needle cap back on used pre-filled syringes to avoid needle-stick injuries.

*Examine the injection site.*

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply a plaster if needed.

**If a second injection is required:**

- Repeat steps 1 to 3. Choose a different site for the second injection.
- Check your prescription for your dose. If your dose is 90 mg, you will receive either one 90 mg pre-filled syringe or two 45 mg pre-filled syringes.
- If you receive two 45 mg pre-filled syringes for a 90 mg dose, you will need to give yourself a second injection right after the first.

**Step 4: After the injection**

Discard the used pre-filled syringe and other supplies in a sharps disposal container.

Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

- **Do not** reuse the pre-filled syringe
- **Do not** recycle pre-filled syringes or throw them into household waste.

**Please contact your health professional if you have any questions about WEZLANA**