

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	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are using WEZLANA.● Tell your doctor about your medical conditions before each treatment.● Tell your doctor if you become pregnant while using WEZLANA.
Things you should not do	<ul style="list-style-type: none">● 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.
Looking after your medicine	<ul style="list-style-type: none">● Keep WEZLANA in a refrigerator between (2°C and 8°C). Do not freeze.

- Do not shake.
- 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](#)

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 is available in vial and pre-filled syringe, see the detailed “Instructions for Use” provided with the medicine for instructions about the right way to store, prepare and give your WEZLANA injections at home.

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.

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°C and 8°C).
- 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°C for one period of up to 30 days.

- Write the date on the carton, when removed from the refrigerator.
- Once pre-filled syringe has been stored at room temperature, do not put it back in the refrigerator.

- Throw away pre-filled syringe 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 (as relevant)

Throw away pre-filled syringe 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
<p>Gut and digestion:</p> <ul style="list-style-type: none">• diarrhoea• nausea, vomiting• dental infections or sores in your mouth <p>Lungs and Upper airway:</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● upper respiratory infections such as sinus and colds ● Sore throat ● Blocked or stuffy nose <p>Injection site:</p> <ul style="list-style-type: none"> ● pain or redness ● bleeding, bruising, hardness, swelling and itch <p>Skin:</p> <ul style="list-style-type: none"> ● acne ● painful rash, blisters ● eczema ● itching (pruritis) ● cellulitis ● shedding or peeling of the skin ● A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever <p>Other:</p> <ul style="list-style-type: none"> ● tiredness, fatigue ● dizziness, headaches 	

Less serious side effects	What to do
<ul style="list-style-type: none"> ● back, joint or muscle pain ● vaginal yeast (fungal) infection ● feeling weak 	

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> ● shortness of breath ● wheezing or difficulty breathing ● swelling of the face, lips, tongue or other parts of the body <p>Infusion related reaction:</p> <ul style="list-style-type: none"> ● fever or chills ● rash, itching or hives on the skin ● chest pain 	<p>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.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • change in blood pressure <p>Other:</p> <ul style="list-style-type: none"> • depression • bronchitis or pneumonia 	

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 polysorbate 80 sucrose 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 histidine histidine hydrochloride monohydrate

	methionine polysorbate 80 sucrose water for injections
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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 January 2024.