

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**ADTRALZA**[®] (tralokinumab injection)

Solution for subcutaneous injection
Single-use pre-filled syringe (150 mg/1 mL)

Read this carefully before you start taking **Adtralza** 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 **Adtralza**.

What is Adtralza used for?

Adtralza is used to treat adults and adolescents who have a moderate-to-severe skin condition called 'atopic dermatitis' (eczema) that causes symptoms such as dry, itchy, scaly skin. Adtralza is used for adults and adolescents who cannot be adequately treated using therapies that are applied on the surface of the skin (topical).

Adtralza can be used with or without other drugs called topical corticosteroids (TCS) or topical calcineurin inhibitors (TCIs).

It is not known if Adtralza is safe and effective in children under 12 years old.

How does Adtralza work?

Adtralza contains the active substance tralokinumab.

Adtralza works by stopping a protein in the body called IL-13, which is found in higher amounts in people with atopic dermatitis. This can result in reduced inflammation, improved condition of your skin, and reduced itch, redness and scaling.

What are the ingredients in Adtralza?

Medicinal ingredients: tralokinumab

Non-medicinal ingredients: acetic acid, polysorbate 80, sodium acetate trihydrate, sodium chloride, and water for injection.

Adtralza comes in the following dosage forms:

Adtralza comes as a single-use pre-filled syringe with needle guard.

Each syringe of Adtralza contains 150 mg of tralokinumab in 1mL solution (150 mg/mL).

The components of the pre-filled syringe or the needle cover are NOT made with natural rubber latex (NRL), dry natural rubber (DNR), or any derivatives (of NRL or DNR).

Do not use Adtralza if:

You are allergic to tralokinumab or to any of the other ingredients of this medicine.

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

- have eye problems (e.g., itching, redness).
- have a parasitic worm (helminth) infection.
- are scheduled to receive any vaccinations. You should **not** receive a “live vaccine” if you are treated with Adtralza.
- are pregnant or plan to become pregnant. It is not known if Adtralza will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Adtralza will pass into your breast milk and harm your baby.

Other warnings you should know about:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use Adtralza for a condition for which it was **not** prescribed. **Do not** give Adtralza to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Adtralza that is written for health professionals.

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

How to take Adtralza:

- Your healthcare professional may decide if you or a caregiver can give the injections of Adtralza. **Do not** try to inject Adtralza until your healthcare professional shows you the right way.
- See the detailed “Instructions for Use” that comes with Adtralza for information on how to prepare and inject Adtralza. It also shows how to properly store and throw away used Adtralza pre-filled syringes.
- Use Adtralza exactly as your healthcare professional has told you.
- Adtralza is given as an injection under the skin (subcutaneous injection). **Do not** inject into your muscle.
- Your healthcare professional may prescribe other medicines to use with Adtralza. Use the other medicines exactly as your healthcare professional has told you.

Usual dose:

Each pre-filled syringe contains 150 mg of Adtralza to be injected under the skin (subcutaneously).

Your treatment with Adtralza should be started by a healthcare professional who has experience in the treatment of atopic dermatitis.

- The initial dose is 600 mg (four 150 mg injections).
- Afterwards, a maintenance dose of 300 mg (two 150 mg injections) should be given every other week.

- Your healthcare professional may consider treating you with a maintenance dose every four weeks depending on how you respond to your treatment with Adtralza.

This is a long-term treatment. Your healthcare professional will regularly check your condition to see if the treatment is effective.

Overdose:

There is no specific treatment for Adtralza overdose.

If you think you, or a person you are caring for, have taken too much Adtralza, 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, administer the dose as soon as possible. **Do not** wait for the next planned dose. After that, continue dosing at the regular scheduled time. If you are not sure what to do, contact your healthcare professional for guidance.

What are possible side effects from using Adtralza?

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

Very rarely, drugs can cause serious side effects, including allergic (hypersensitivity) reactions and anaphylactic reaction. You must look out for signs of these conditions (which can include breathing problems, swelling of the face, mouth, and tongue, fainting, dizziness, feeling lightheaded (low blood pressure), fever, hives, itching, skin rash) while you are taking Adtralza.

If you notice any of the signs above, stop using Adtralza and get emergency help right away.

The most common side effects of Adtralza include:

- Upper respiratory tract infections (i.e., common cold and sore throat)
- Injection site reactions: itching, pain, redness, tenderness, warmth in the area around the injection
- Eye problems: eye inflammation, including redness, swelling, and itching. Tell your healthcare professional if you have any worsening eye problems, including eye pain or changes in vision.

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	
RARE			
Allergic reactions (hypersensitivity): Breathing problems, difficulty swallowing, swelling of the face, mouth, and tongue, fainting, dizziness, feeling lightheaded (low blood pressure), fever, hives, itching, skin rash			✓

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 Adtralza in its original carton to protect from light. **Do not** put Adtralza pre-filled syringes into direct sunlight or expose to heat.
- Store Adtralza in a refrigerator between 2°C and 8°C.
 - **Do not** freeze Adtralza pre-filled syringes. **Do not** use syringes if they have been frozen.
- If necessary, you may keep Adtralza pre-filled syringes at room temperature up to 30°C for a maximum of 14 days, within the expiration date period of the product.
 - **Do not** store above 30°C.
 - If the carton needs to be removed permanently from the refrigerator, record the date of removal on the outer carton. Throw away syringes in a puncture resistant container if not used within 14 days of storage at room temperature.
 - **Do not** put syringes back in the refrigerator once they have reached room temperature.
- **Do not** shake Adtralza pre-filled syringes.
- **Do not** use Adtralza after the expiration date shown on the outer box or syringe label. If it has expired, return the whole pack to the pharmacy.

- Keep out of reach and sight of children.

If you want more information about Adtralza:

- 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.leo-pharma.ca, or by calling 1-800-263-4218.

This leaflet was prepared by LEO Pharma Inc.

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INSTRUCTIONS FOR USE

PrADTRALZA® (tralokinumab injection)

Solution for subcutaneous injection
Single-use pre-filled syringe

Read the following Instructions for Use before you start using Adtralza pre-filled syringes and each time you get a new package. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

Keep these Instructions for Use and refer to them as needed.

Each pre-filled syringe contains 150 mg of Adtralza.

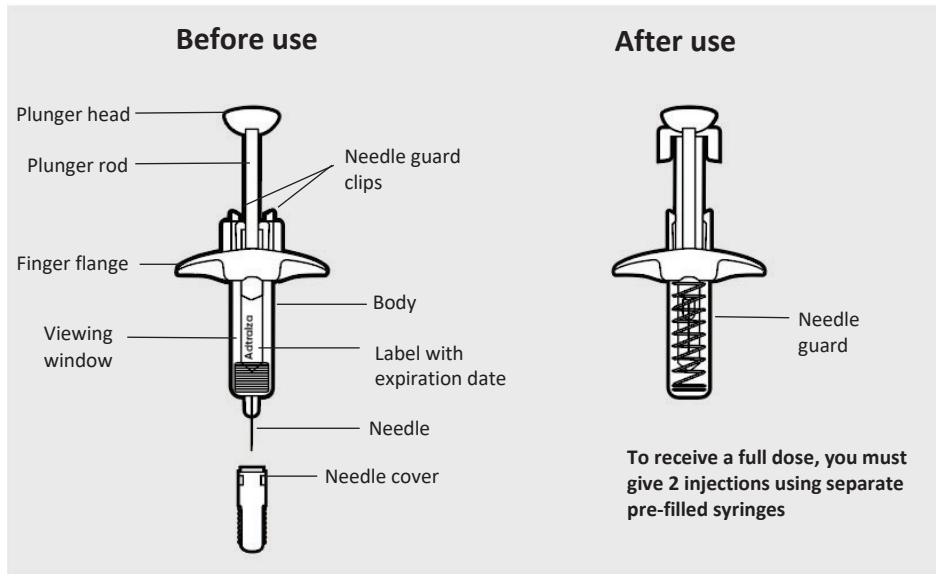
Adtralza pre-filled syringes are for single-use only.

IMPORTANT INFORMATION

Important information you need to know before injecting Adtralza:

- Your healthcare professional should show you how to prepare and inject Adtralza before you make your first injection.
- **Do not** inject yourself or someone else until you have been shown how to inject Adtralza the right way.
- Talk to your healthcare professional if you have any questions about how to inject Adtralza the right way.
- **To receive your full dose, you will need to give more than 1 Adtralza injection.**
 - To get your full initial dose of **600 mg**, you will need to give **4** injections at different injection sites within the same body area.
 - To get your full maintenance dose of **300 mg**, you will need to give **2** injections at different injection sites within the same body area.
- **It is recommended to rotate the injection area (see Figure 2a) with each new set of injections.**
- The Adtralza pre-filled syringes have a needle guard that will automatically cover the needle after the injection is finished.
- For injection directly into the fatty layer under the skin (subcutaneous injection only).
- **Do not** remove the needle cover until just before you give the injection.
- **Do not** share or reuse your Adtralza pre-filled syringes.
- **Do not** inject through clothes.

ADTRALZA PRE-FILLED SYRINGE PARTS:

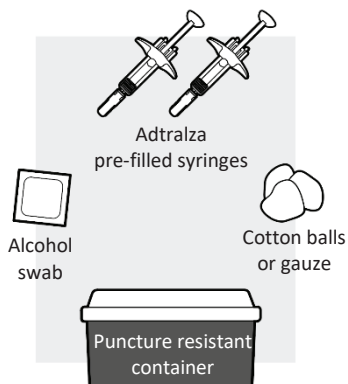


HOW TO STORE ADTRALZA

- Store Adtralza pre-filled syringes in a refrigerator between 2°C and 8°C.
- Store Adtralza pre-filled syringes in the original package and protect from light and heat until you are ready to use them.
- **Do not** freeze Adtralza pre-filled syringes. **Do not** use if they have been frozen.
- Adtralza can be stored at room temperature up to 30°C for up to 14 days, within the expiration date period of the product. Discard syringes if left out of the refrigerator for more than 14 days.
- **Keep Adtralza and all medicines out of the sight and reach of children.**

STEP 1: SETTING UP ADTRALZA FOR INJECTION

1a: Gather the supplies needed for your injections



For each Adtralza dose you will need:

- A clean flat, well-lit work surface, like a table
- 1 Adtralza carton that contains 2 pre-filled syringes
- An alcohol swab (not included in the carton)
- Clean gauze pads or cotton balls (not included in the carton)
- A puncture resistant (sharps) disposal container (not included in the carton)

See Step 5 "DISPOSING OF ADTRALZA" at the end of the Instructions for Use.

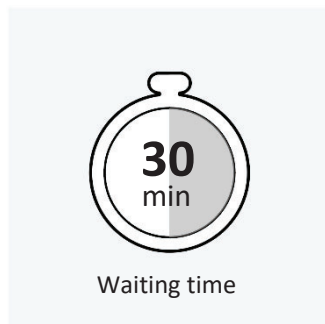
1b: Take the Adtralza carton out of the refrigerator



- **Check the expiry date (EXP) on the carton. Do not** use if the expiry date on the carton has passed.
- Check to make sure the seal on the Adtralza carton is intact. **Do not** use the Adtralza pre-filled syringes if the seal on the carton is broken.

Do not use the Adtralza pre-filled syringes if the syringes have been stored at room temperature for more than 14 days.

1c: Let the Adtralza pre-filled syringes warm up to room temperature

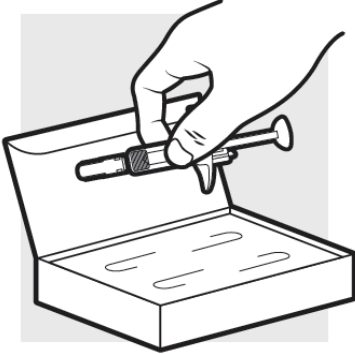


Set the Adtralza carton on a flat surface and wait 30 minutes before you inject, in order to let the pre-filled syringes warm up to room temperature (20°C to 30°C). This will help to reduce discomfort and make it easier to inject Adtralza.

- **Do not** microwave the pre-filled syringes, run hot water over them, or leave them in direct sunlight.
- **Do not** shake the syringes.
- **Do not** remove the needle cover on the pre-filled syringes until you have reached Step 3 and are ready to inject.

- **Do not** put the syringes back in the refrigerator once they have reached room temperature.

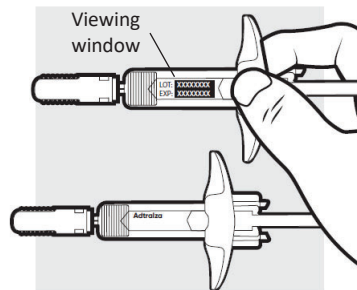
1d: Remove the Adtralza pre-filled syringes from the carton



Remove the **2** Adtralza pre-filled syringes one by one from the carton by holding the body (not the plunger rod) of each pre-filled syringe.

- **Do not** touch the needle guard clips to prevent activating the safety device (needle guard) too soon.
- **Do not** remove the needle cover on the pre-filled syringes until you have reached Step 3 and are ready to inject.

1e: Inspect the 2 Adtralza pre-filled syringes

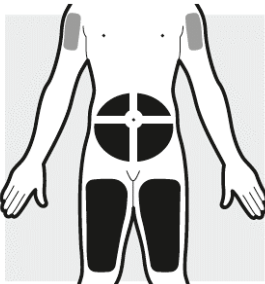


- Make sure the Adtralza name appears on the labels.
 - Check the expiry date printed on the syringes.
 - Check the medicine through the viewing window. The medicine inside should be clear to opalescent, colourless to pale yellow.
 - **Do not** use the Adtralza pre-filled syringes if:
 - the expiry date printed on the syringes has passed
 - the medicine is cloudy, discoloured, or has particles in it
 - they look damaged or have been dropped
- In these cases, dispose of the syringes in a puncture resistant (sharps) container and use new syringes.

- You may see small air bubbles in the liquid. This is normal. You do not need to do anything about it.

STEP 2: CHOOSING AND PREPARING THE INJECTION AREA

2a: Choose the area for your injections



- Injection by caregiver only
- Self-injection or by caregiver

- You may inject into:
 - your stomach area (abdomen)
 - your thighs
 - your upper arm. To inject into your upper arm, you will need a caregiver to give you the injections.
- **Do not** inject where the skin is tender, bruised, scaly, scarred, damaged, hard or covered with eczema.
- **Do not** inject within 5 cm of your belly button (navel).
- **Choose a different body area with each following set of injections. Do not use the same body area 2 times in a row.**

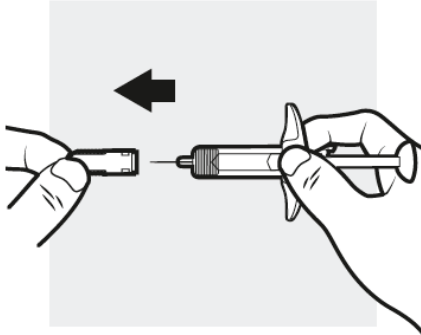
2b: Wash your hands and prepare your skin



- Wash your hands with soap and water.
- Clean the injection area for the 2 injections with an alcohol swab using a circular motion.
 - Let the area dry completely.
 - **Do not** blow or touch the cleaned area before injecting.

STEP 3: INJECTING ADTRALZA

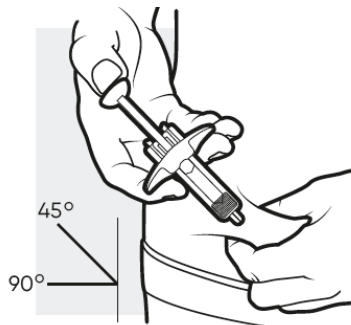
3a: Pull off the needle cover from the pre-filled syringe



Hold the pre-filled syringe body with one hand, pull the needle cover straight off with your other hand and throw it away in the puncture resistant (sharps) container.

- **Do not try to recap the Adtralza pre-filled syringes.**
- **Do not** hold the plunger rod or plunger head while removing the needle cover.
- You may see a drop of liquid at the end of the needle. This is normal.
- **Do not** touch the needle, or let it touch any surface. If either of these occur, throw away the syringe in a puncture resistant (sharps) container and get a new one.

3b: Insert the needle



With one hand, gently pinch and hold a fold of skin where you cleaned the injection area. With the other hand, insert the needle completely into your skin at a 45 to 90 degree angle.

3c: Inject the medicine



Use your thumb to firmly push down the plunger head all the way down. All the medicine is injected when you cannot push the plunger head any further.

3d: Release and remove



Lift your thumb off the plunger head. The needle will automatically move back inside the syringe body and lock into place.

- Place a dry cotton ball or gauze pad over the injection area for a few seconds. **Do not** rub the injection area. If needed, cover the injection area with a small bandage.
- There may be a small amount of blood or liquid where you injected. This is normal. Throw away the used Adtralza pre-filled syringe in a puncture resistant (sharps) container. **See Step 5 “DISPOSING OF ADTRALZA”.**

STEP 4: INJECTING THE NEXT SYRINGE



To get your full prescribed dose, you will need to give more than 1 injection.

- To get your full initial dose of **600 mg**, you will need to give **4** injections.
- To get your full maintenance dose of **300 mg**, you will need to give **2** injections.

Get a new Adtralza pre-filled syringe and repeat Steps 3 and 5 for each injection you need to give for your full prescribed dose.

Note

Make sure each injection is at least 3 cm from the previous injection site and within the same body area.

STEP 5: DISPOSING OF ADTRALZA



- Put the used Adtralza pre-filled syringes in a puncture resistant (sharps) container right away after use.
 - **Do not** throw away the Adtralza pre-filled syringes in your household trash.
- If you do not have a puncture resistant (sharps) container, you can use a household container that is:
 - made of heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-proof lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-proof, and
 - properly labeled to warn of hazardous waste inside the container.
- When your puncture resistant (sharps) container is almost full, you will need to follow your community guidelines for the right way to get rid of the container.
- **Do not** recycle your used puncture resistant (sharps) container.