

Patient leaflet

Information about treatment
with Adtralza[®] (tralokinumab)
pre-filled pen or syringe

Contents

This leaflet provides information about tralokinumab, such as how the medicine works and how you should use it.

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What is atopic dermatitis (eczema)?

Atopic dermatitis (eczema) is the most common type of eczema.

Symptoms

Eczema causes itchy patches on your skin. You may also suffer from flaking, bumps, blisters, cracks and scabs.

Cause

- Eczema affects the skin's ability to protect itself against external substances.
- Your immune system may react excessively to these substances, causing inflammation of the skin. This inflammation causes the symptoms of eczema.

Information about tralokinumab



What is tralokinumab?

Tralokinumab is a medicine used in the treatment of atopic dermatitis (eczema). Adults and adolescents from 12 years of age may use this medicine.

- **Tralokinumab is a biologic**

This means that it is a medicine produced from natural proteins. Proteins are important building blocks in your body. They ensure that your body functions normally.

- **Tralokinumab is a systemic treatment**

The proteins in tralokinumab get to work in your own immune system to tackle the cause of inflammation.



How does tralokinumab work?

The immune system of people with eczema produces too much of the protein IL-13. This can cause inflammation.

Research has show that the more IL-13 a person produces, the more severe their eczema is.



Tralokinumab blocks the action of IL-13

As a result, this protein can no longer cause inflammation, thereby reducing itching and redness.

Potential side effects

What are the potential side effects of tralokinumab?

As is the case with any medicine, tralokinumab can cause side effects. The package insert provides a summary of the potential side effects of tralokinumab.

The most common side effects of tralokinumab are:

- upper respiratory tract infections, such as a cold
- a skin reaction at the injection site
- conjunctivitis (inflammation of the eye)

These are the most common side effects, but that does not mean that you will also develop these side effects.

Call a doctor immediately if you experience symptoms of a severe allergic reaction, such as:

- difficulty breathing
- swelling of the face, mouth or tongue
- skin rash
- dizziness or fainting



What if you experience side effects? Tell your doctor, pharmacist or nurse. This also applies to potential side effects that are not listed in this leaflet or in the package insert.

You can also report side effects to the Netherlands Pharmacovigilance Centre Lareb. You can report side effects at www.lareb.nl.

How should you use tralokinumab?

Tralokinumab is easy to use

You can inject tralokinumab using a pen or a syringe. These are pre-filled when you remove them from the packaging.



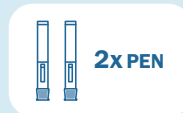
Together with your doctor, you will decide whether you may inject tralokinumab yourself. You may only inject tralokinumab yourself **once** your doctor or nurse has taught you how to do this.

It is also important that you feel comfortable injecting yourself. If you find it unpleasant to inject the medicine yourself, then your doctor or nurse can help you.

Pen

Initial dose:

The first time, you will use **2 pens** containing **300 mg each**.



This is a one-off higher dose, to achieve the correct concentration of the medicine in your body.

Maintenance:

After this initial dose, you will use **1 pen** containing **300 mg**.

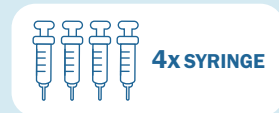


Once every 2 weeks.

Syringe

Initial dose:

The recommended initial dose is **4 administrations of 150 mg each**.



This is a one-off higher dose, to achieve the correct concentration of the medicine in your body.

Maintenance:

After this initial dose, you **will use 2 syringes** containing **150 mg each**.



Once every 2 weeks.

Once the desired treatment effect has been achieved, your doctor will discuss with you the possibility of tapering the injections to once every 4 weeks.



How should you store tralokinumab?

- Store tralokinumab **in the refrigerator**.
- A good storage temperature is between 2°C and 8°C.



Preparations: remove from the refrigerator before injection

- **Remove the** pen from the refrigerator at least 45 minutes before injecting the medicine. The syringe should be removed **at least 30 minutes before injection**.

The pen or syringe must be used at room temperature.

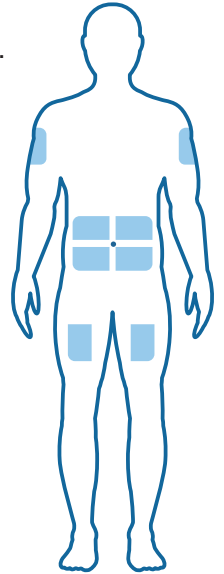
A good temperature is between 18°C and 22°C.

- Place the package on a flat surface.
- **Do not place** the pen or syringe in direct sunlight.

Where should you inject tralokinumab?

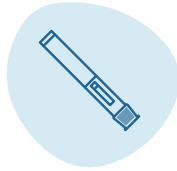
You can inject tralokinumab yourself in your stomach or thigh. You will need someone to help you when injecting in the upper arm.

- **Do not** inject in areas where the skin is sensitive, bruised, flaking or damaged, or in areas with scars.
- **Do not** inject within 5 cm around your belly button.
- Choose a different area of your body for each injection. **Do not** use the same injection site twice in a row.
- In the case of the one-off initial dose, you should inject the pens or syringes in the same part of your body, but you should space them at least 3 cm apart.



Use a different area for each injection

How should you inject tralokinumab using a pen?



- Choose an injection site.
- Remove the cap from the pen.
- Place the pen flat against the skin at an angle of 90 degrees.
- Then press the pen firmly against the skin.
- The injection starts when you hear the first click. Hold the pen firmly in the same position against the skin.
- The second click lets you know that the injection is finished. Keep the pen firmly against the skin for another 5 seconds.
- Remove the pen by carefully pulling it straight up from your skin.
- The needle guard will automatically cover and lock into place over the needle.

Watch the step-by-step instruction video*



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How should you inject tralokinumab using a syringe?



- Choose an injection site.
- Inject both syringes in the same part of your body, but space them at least 3 cm apart.
- Carefully remove the cap from the syringe, making sure that you do not bend the needle. You may see a drop of liquid at the end of the needle – this is normal.
- Use one hand to pinch and hold a fold of skin. Use your other hand to insert the needle at an angle of 45 to 90 degrees.
- Use your thumb to administer the medicine. Press the plunger head down as far as it will go.
- Lift your thumb from the plunger head. The needle will automatically move inside the syringe and lock into place.
- Use the full dose of syringes.
- Dispose of the syringes as instructed by your doctor or nurse.

Watch the step-by-step instruction video*



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What should you do if you miss a dose?

If you miss a dose, you should inject it as soon as you remember. Then continue the injections according to your doctor's schedule.



What should you do if you have injected too much tralokinumab?

If you have accidentally injected more tralokinumab than prescribed, please contact your doctor or nurse.



Can you travel with tralokinumab?

Once you remove the pre-filled pens or syringes from the refrigerator, you can store them at room temperature for a maximum of 14 days. Ensure that the pens are stored at a temperature below 30°C. The temperature of the syringes should remain below 25°C.

Do not use tralokinumab if it has been stored outside of the refrigerator for 14 days or more.



Did you know? You should never dispose of medication yourself. Take the used pens and syringes to your pharmacy.



Keeping track of your injections

After each injection, please record the following:

- **when** you administered the injection.
- **where** you administered the injection.

This makes it easier to remember your tralokinumab treatment and inject a different area every time.



Where can you find more information about injecting?

Please read the package leaflet for more information about preparing and injecting tralokinumab.

Important information to ensure safe use

Tell your doctor if you:

- have other medical conditions.
- have eye problems.
- have a parasitic worm infection.
- are pregnant or wish to become pregnant.
- are breastfeeding or wish to do so.

Please tell your doctor if you are using any other medicines. This includes over-the-counter medicines, herbal products and vitamins.

Do not use Adtralza® if you are allergic to tralokinumab or one of the ingredients. A complete list of ingredients is provided on page 18.

General information to ensure safe use of tralokinumab

- Use tralokinumab exactly as prescribed by your doctor.
- Tralokinumab can be used with or without corticosteroid cream.
- Tralokinumab is supplied in a pre-filled pen or syringe. You can use the pen or syringe only once. You should dispose of the pen or syringe immediately after use.
- You should not use tralokinumab for conditions for which it has not been prescribed.
- Do not give tralokinumab to others. Do not give to others, even if they have the same symptoms as you. It may be harmful to them.



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