


**A step-by-step
guide to
injecting Adbry[®]
(tralokinumab-ldrm)
at home**

Please see Indication and Important Safety Information on pages 18-19 of this brochure and [accompanying](#) Full Prescribing Information, Patient Information, and Instructions for Use in the pocket.



Adbry[®]
(tralokinumab-ldrm)
Injection 150 mg/mL

This Instructions for Use Brochure contains information on how to inject Adbry® (tralokinumab-ldrm).

Read this Instructions for Use Brochure before you start using Adbry prefilled syringes and each time you get a refill. There may be new information, so make sure you check the leaflet that comes in your Adbry carton with the syringes before you inject every time. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

Keep this Instructions for Use Brochure and refer to it as needed.

Each single-dose prefilled syringe contains 150 mg of Adbry. The Adbry prefilled syringes are for single dose only.

What is Adbry?

- Adbry® (tralokinumab-ldrm) injection is a prescription medicine used to treat adults with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. Adbry can be used with or without topical corticosteroids.
- It is not known if Adbry is safe and effective in children.

Do not use Adbry if you are allergic to tralokinumab or to any of its ingredients.

Important information you need to read before injecting

- Your **healthcare professional should show you how** to prepare and inject Adbry using the prefilled syringes **before you inject Adbry for the first time**
- **Do not** inject yourself or someone else until you have been shown how to inject Adbry the right way
- Talk to your healthcare professional if you have any **questions about how to inject** Adbry the right way
- Your healthcare professional will determine if you will receive your **initial loading dose (4 injections) in their office**

- **To receive your full prescribed dose, you will need to give more than 1 Adbry injection**

Initial Loading Dose



To get your full prescribed initial loading dose of **600 mg**, you will need to give **4 injections** at different injection sites within the same body area


At-home Maintenance Dose



To get your full prescribed 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 body area with each new set of injections**
- The Adbry prefilled syringes have a needle guard that will be activated to cover the needle after the injection is finished
- For subcutaneous injection only (inject directly into fatty layer under the skin)
- **Do not** remove the needle cover until just before you give the injection
- **Do not** share or reuse your Adbry prefilled syringes
- **Do not** inject through clothes

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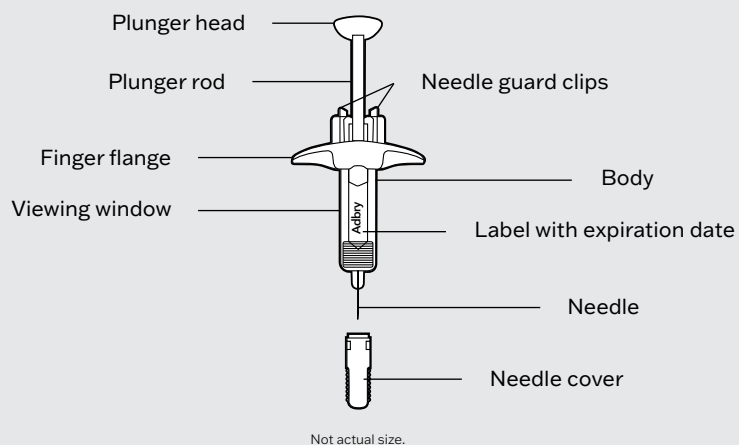

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Prefilled syringe parts (see Figure A):

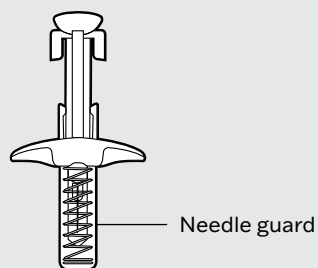
Figure A

To receive your full initial loading dose, you must give 4 injections and to receive your full maintenance dose you must give 2 injections using separate prefilled syringes.

BEFORE USE



AFTER USE



Storing



- Store Adbry® prefilled syringes in a refrigerator between 2°C to 8°C (36°F to 46°F)
- Store Adbry prefilled syringes in the original carton and protect from light until you are ready to use them
- Adbry can be stored in the original carton at room temperature up to 30°C (86°F) for up to 14 days. Throw away (dispose of) syringes if left out of the refrigerator for more than 14 days
- **Do not** freeze Adbry prefilled syringes. **Do not** use if they have been frozen
- **Do not** shake the Adbry prefilled syringe
- **Do not** heat the Adbry prefilled syringe
- **Do not** put the Adbry prefilled syringe into direct sunlight
- **Keep Adbry prefilled syringes and all medicines out of the reach of children**



Not actual size.

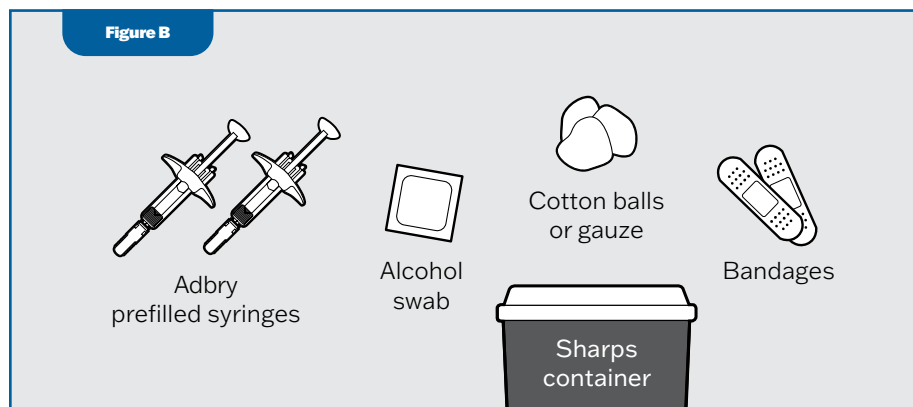
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Step 1: Setting up the maintenance injection

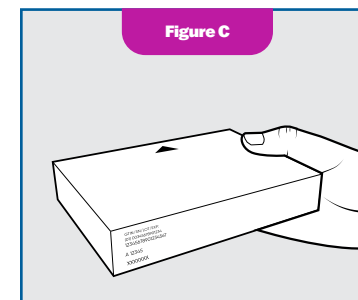
1a Gather the supplies needed for your injection. For each Adbry® dose you will need (see Figure B):

- A clean, flat, well-lit work surface, like a table
- **1 Adbry carton** that contains **2 Adbry prefilled syringes**
- An alcohol swab (not included in the carton)
- Clean gauze pads or cotton balls (not included in the carton)
- Bandages (not included in the carton)
- A puncture-resistant sharps disposal container (not included in the carton).
See Step 5 "Disposing" at the end of this Instructions for Use Brochure



1b Take the Adbry prefilled syringe carton out of the refrigerator

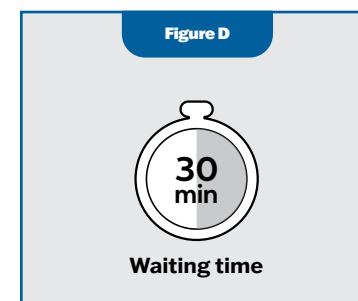
- **Check the expiration date (EXP) on the carton (see Figure C).** **Do not** use if the expiration date on the carton has passed
- Check to make sure the seal on the Adbry carton is intact. **Do not** use the Adbry prefilled syringes if the seal on the carton is broken




1c Let the Adbry prefilled syringes warm up to room temperature (see Figure D)

Set the Adbry carton on the flat surface and wait **30 minutes** before you inject Adbry to let the prefilled syringes **warm up to room temperature**, 20°C to 30°C (68°F to 86°F). This will **help to reduce discomfort and make it easier to inject Adbry**.

- **Do not** microwave the prefilled 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 prefilled 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



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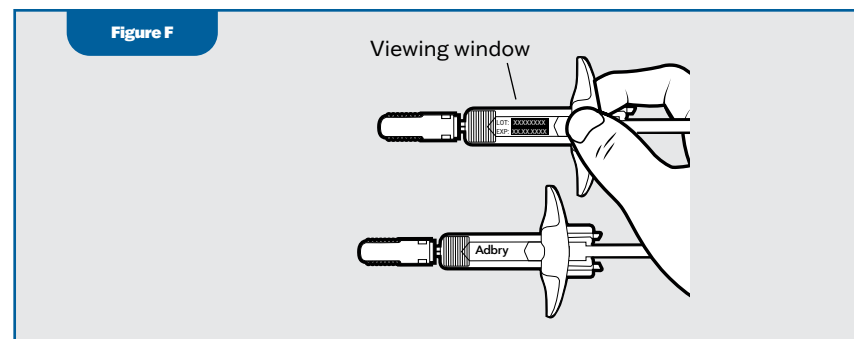
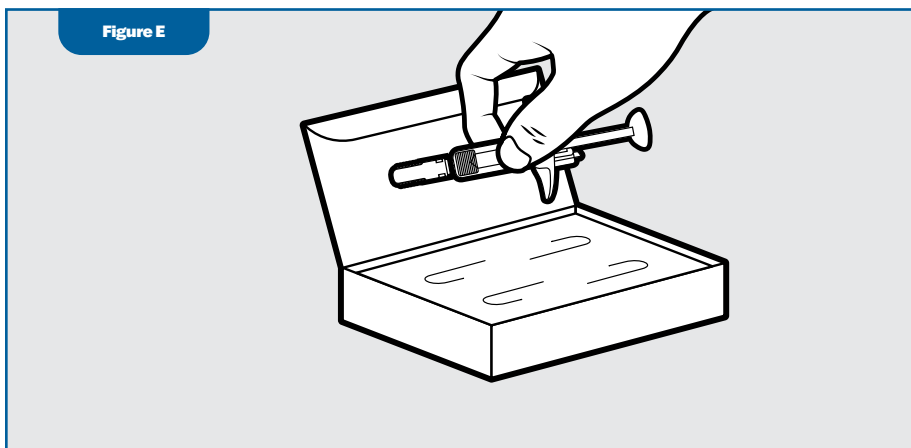

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Step 1: Setting up the injection (continued)

1d Remove the Adbry® prefilled syringes from the carton

Remove the **2 Adbry prefilled syringes** one by one from the carton by **grasping the body (not the plunger rod)** of the Adbry prefilled syringes (see Figure E).

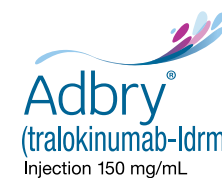
- **Do not** touch the needle guard clips to keep from activating the safety device (needle guard) too soon
- **Do not** remove the needle cover on the prefilled syringes until you have reached Step 3 and are ready to inject



1e Inspect the 2 Adbry prefilled syringes (see Figure F)

- Make sure **Adbry** appears on the **labels**
- **Check the expiration date** printed on the syringes
- **Check the medicine** through the viewing windows. The medicine inside should be **clear to slightly pearly and colorless to pale yellow**
- **Do not** use the Adbry prefilled syringes, and throw away and get new ones if:
 - The expiration date printed on the syringes has passed
 - The medicine is cloudy, discolored, or has particles in it
 - They look damaged or have been dropped
- You **may see small air bubbles in the liquid**. This is **normal**. You do not need to do anything about it

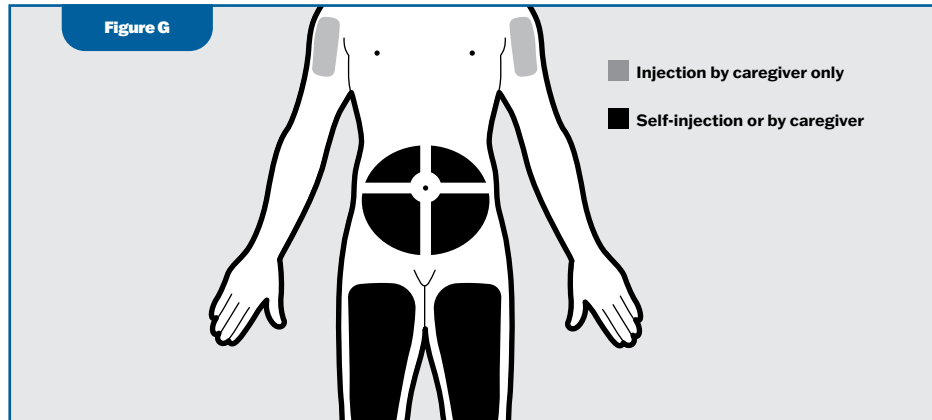
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Step 2: Choosing and preparing an injection area

2a Choose the area for your injections (see Figure G)

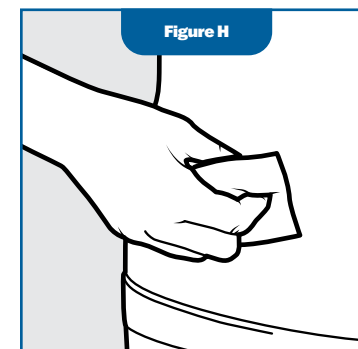
- **You may inject into:**
 - Your stomach area (abdomen)
 - Your thighs
 - Your upper arm. To inject into your upper arm, you will need a caregiver to give you the injections
- **Do not** inject within 2 inches (5 cm) of your belly button (navel)
- **Do not** inject where the skin is tender, damaged, bruised, or scarred




- **Rotate the 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 (see Figure H)

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



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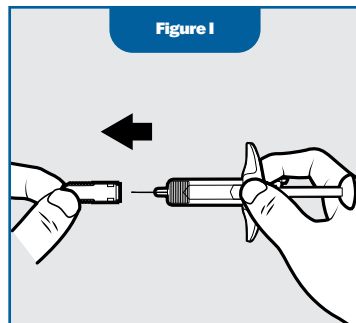

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Step 3: Injecting

3a Pull off the Adbry® needle cover

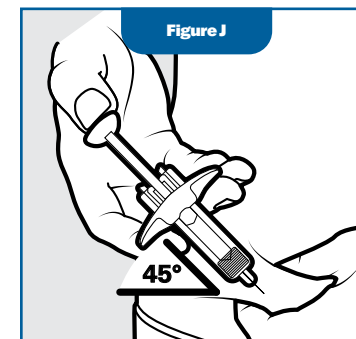
Hold the Adbry prefilled syringe body with one hand, pull the needle cover straight off with your other hand (see Figure I), and throw it away in the sharps container.

- **Do not try to recap the Adbry prefilled 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 and get a new one



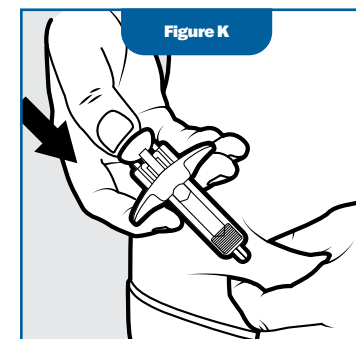
3b Insert the needle

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 at about a 45-degree angle into your skin (see Figure J).




3c Inject the medicine

Use your thumb to firmly push down the plunger head all the way down (see Figure K). All of the medicine is injected when you cannot push the plunger head any further.



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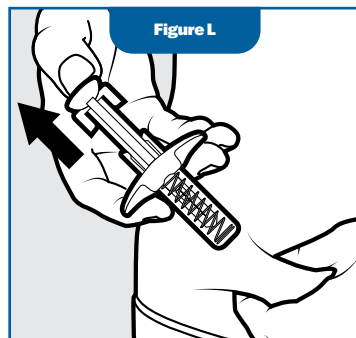
Step 3: Injecting (continued)

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 (see **Figure L**).

- Place a dry cotton ball or gauze pad over the injection site for a few seconds. **Do not** rub the injection site. If needed, cover the injection site with a small bandage
- There may be a small amount of blood or liquid where you injected. This is normal

Throw away the used Adbry® prefilled syringe in the sharps disposal container. See **Step 5 “Disposing.”**

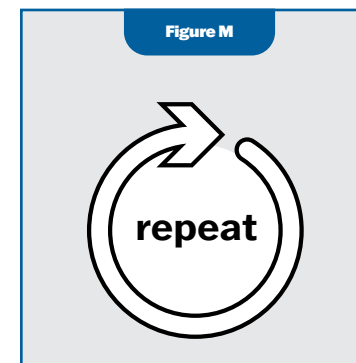


Step 4: Injecting the next syringe

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

- **Initial Loading Dose:** To get your full prescribed initial dose of **600 mg**, you will need to give **4 injections**
- **Maintenance Dose:** To get your full prescribed dose of **300 mg**, you will need to give **2 injections every other week**. Use Adbry as prescribed by your healthcare professional


Get a new Adbry prefilled syringe and repeat Steps 3 and 5 (see Figure M) for each injection you need to give for your full prescribed dose.



NOTE

Make sure each injection is at least 1 inch (3 cm) from the prior injection site and within the same body area.

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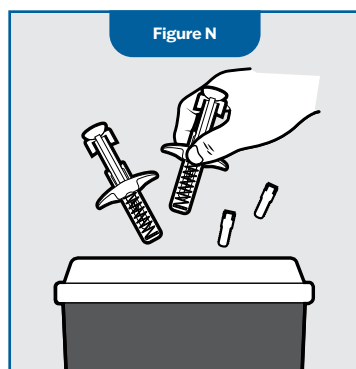

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Step 5: Disposing

- 5 • Put the used Adbry® prefilled syringes in an FDA-cleared sharps disposal container right away after use (see Figure N). **Do not** throw away the Adbry prefilled syringes in your household trash

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

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



- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **Do not** recycle your used sharps disposal container



To request a **free sharps container**, call the Adbry® Advocate™ Program at 844-MY-ADBRY (844-692-3279)


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Adbry® advocate™

Enroll in the Adbry® Advocate™ Program today

The Adbry® Advocate™ Program may provide patients with access to a dedicated Nurse Advocate*†, helpful treatment resources, and, if eligible, savings and support programs.

*Nurse Advocates cannot give any medical advice.

†Restrictions apply. See full terms, conditions, and eligibility criteria at www.ADBRY.com/terms-conditions.



Scan to save number

Having your Nurse Advocate's number saved in your phone can help you easily identify when they call to discuss important information.

844-MY-ADBRY (844-692-3279)

www.ADBRY.com

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Indication and Important Safety Information

What is Adbry?

- Adbry® (tralokinumab-ldrm) injection is a prescription medicine used to treat adults with moderate-to-severe atopic dermatitis (eczema) that is not well controlled with prescription therapies used on the skin (topical), or who cannot use topical therapies. Adbry can be used with or without topical corticosteroids.
- It is not known if Adbry is safe and effective in children.

Do not use Adbry if you are allergic to tralokinumab or to any of its ingredients.

What should I discuss with my healthcare provider before starting Adbry?

Tell your healthcare provider about all your medical conditions, including if you:

- have eye problems.
- have a parasitic (helminth) infection.
- are scheduled to receive any vaccinations. You should not receive a “live vaccine” if you are treated with Adbry.
- are pregnant or plan to become pregnant. It is not known whether Adbry will harm your unborn baby. There is a pregnancy exposure registry for women who use Adbry during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. If you are pregnant or become pregnant while taking Adbry, you are encouraged to enroll in the registry. You or your healthcare provider can get information and enroll you in this registry by calling 1-877-311-8972 or visiting <https://mothertobaby.org/ongoing-study/adbry-tralokinumab/>.
- are breastfeeding or plan to breastfeed. It is not known whether Adbry passes into your breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use Adbry?

- **See the detailed “Instructions for Use” that comes with Adbry for information on how to prepare and inject Adbry and how to properly store and throw away (dispose of) used Adbry prefilled syringes.**
- Use Adbry exactly as prescribed by your healthcare provider.
- Your healthcare provider will tell you how much Adbry to inject and when to inject it.
- Adbry comes as a single-dose (150 mg) prefilled syringe with needle guard.

How should I use Adbry? (cont’d)

- Adbry is given as an injection under the skin (subcutaneous injection).
- If your healthcare provider decides that you or a caregiver can give the injection of Adbry, you or your caregiver should receive training on the right way to prepare and inject Adbry. **Do not** try to inject Adbry until you have been shown the right way by your healthcare provider.
- If you miss a dose, inject the missed dose as soon as possible, then continue with your next dose at your regular scheduled time.
- If you inject more Adbry than prescribed, call Poison Control at 1-800-222-1222.
- Your healthcare provider may prescribe other medicines to use with Adbry. Use the other prescribed medicines exactly as your healthcare provider tells you to.

What are the possible side effects of Adbry?

Adbry can cause serious side effects including:


- **Allergic reactions (hypersensitivity), including a severe reaction known as anaphylaxis.** Stop using Adbry and tell your healthcare provider or get emergency help right away if you get any of the following symptoms:
 - breathing problems
 - swelling of the face, mouth, and tongue
 - itching
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - skin rash
 - hives
- **Eye problems.** Tell your healthcare provider if you have any worsening eye problems, including eye pain or changes in vision.

The most common side effects of Adbry include:

- Eye and eyelid inflammation, including redness, swelling, and itching
- Injection site reactions
- High count of a certain white blood cell (eosinophilia)

These are not all of the possible side effects of Adbry. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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