

INSTRUCTIONS FOR USE

TALTZ® [tol-t-s] (ixekizumab) injection, for subcutaneous use Autoinjector

This Instructions for Use contains information on how to inject TALTZ.



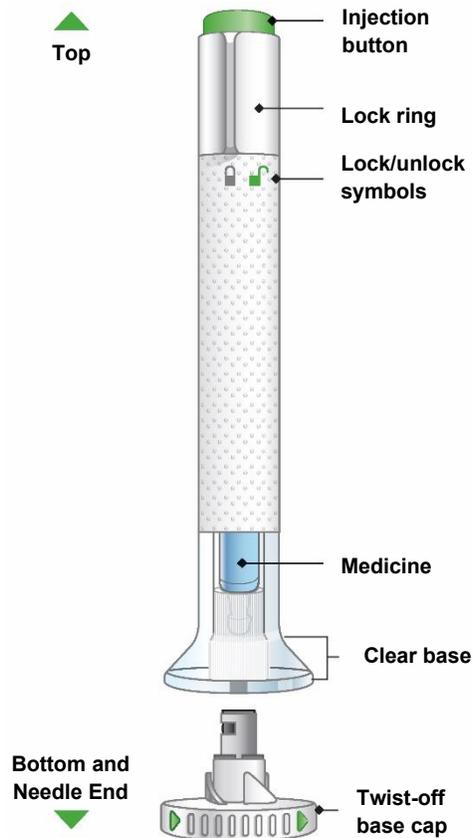
Important Information You Need to Know Before Injecting TALTZ

- Your healthcare provider or nurse should show you how to prepare and inject TALTZ using the autoinjector. **Do not** inject yourself or someone else until you have been shown how to inject TALTZ.
- You and your caregiver should read this Instructions for Use before you start using TALTZ and each time you get a refill. Keep the Instructions for Use and refer to them as needed.
- Each TALTZ autoinjector contains 1 dose of TALTZ. **The autoinjector is for one-time use only.**
- The autoinjector contains glass parts. Handle autoinjector carefully. If you drop it on a hard surface, do not use it. Use a new TALTZ autoinjector for your injection.
- Your healthcare provider may help you decide where on your body to inject your dose. **Do not** give an injection in an area of the skin that is tender, bruised, red or hard, or in an area of skin that is affected by psoriasis. Read the “**Choose your injection site**” section of these instructions to help you choose which area can work best for you.
- If you have vision or hearing problems, **do not** use TALTZ autoinjector without help from a caregiver.

INSTRUCTIONS FOR USE

Before you use the TALTZ autoinjector, read and carefully follow all the step-by-step instructions.

Parts of the TALTZ autoinjector



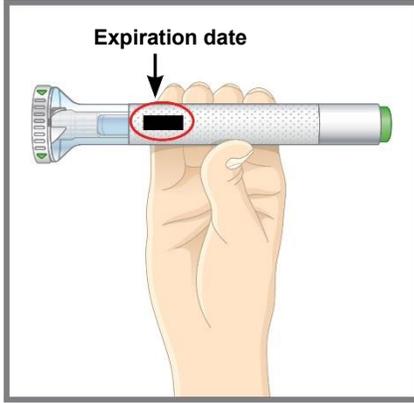
Step 1 Preparing to Inject TALTZ

- Step 1a**
- **Take the TALTZ autoinjector from the refrigerator.**
 - Remove the autoinjector from the package. Put the original package with any unused autoinjectors back in the refrigerator.
 - Leave the base cap on until you are ready to inject.
 - **Wait 30 minutes** to let the autoinjector warm to room temperature before you use it.
 - **Do not** microwave the autoinjector, run hot water over it, or leave it in direct sunlight.
 - **Do not** shake the autoinjector.



Step 1b Gather the supplies needed for your injection:

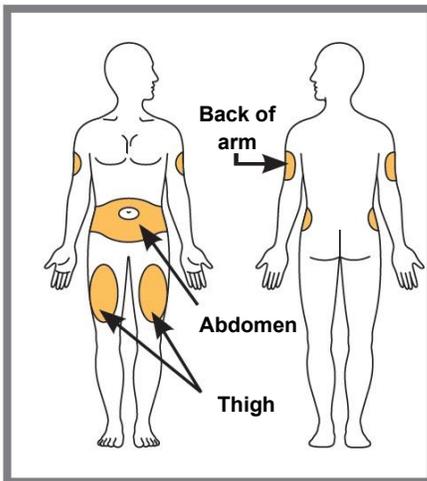
- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps disposal container. See “**Disposing of TALTZ.**”

Step 1c**Figure A****Inspect the autoinjector.**

- Make sure the name **TALTZ** appears on the label.
- The medicine inside should be clear. Its color may be colorless to slightly yellow.

Do not use the autoinjector, and dispose of as directed by your healthcare provider or pharmacist if:

- the expiration date printed on the label has passed (see **Figure A**).
- it looks damaged.
- the medicine is frozen.
- the medicine is cloudy, discolored, or has small particles. The medicine should look clear and colorless to slightly yellow.

Step 1d Wash your hands with soap and water before you inject TALTZ.**Step 1e****Figure B****Choose your injection site.**

You may inject in your stomach area (abdomen) or in your thigh, or in the back of your arm (see **Figure B**). To inject in your arm, you will need someone to help you.

Do not give an injection into areas where the skin is tender, bruised, red or hard, or in an area of skin that is affected by psoriasis.

Do not inject within 1 inch of the navel (belly button).

Alternate your injection sites.

- **Do not** inject in the exact same spot every time. For example, if your last injection was in your left thigh, your next injection should be in your right thigh, your abdomen, or the back of either arm.
- Talk with your healthcare provider about where on your body to best inject TALTZ.

Step 1f Prepare your skin. Clean your injection site with an alcohol wipe. Let the injection site dry before you inject TALTZ.

Step 2 Injecting TALTZ

Step 2a

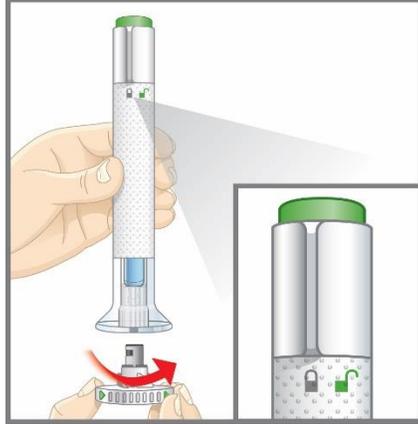


Figure C

Make sure the lock ring is in the lock position.

- Leave the base cap on until you are ready to inject.
- **Do not** touch the needle.

Twist off the base cap in the direction of the arrows (see Figure C).

- Throw the base cap in the trash. You will not need to put the base cap back on. If you do, you could damage the needle or stick yourself by accident.

Step 2b

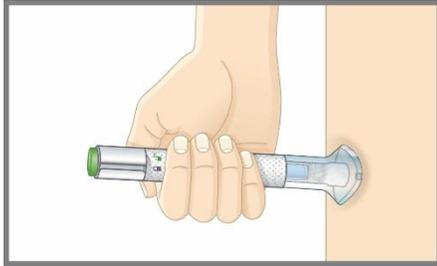


Figure D

Place the clear base flat and firmly against your skin at the injection site (see Figure D).

Step 2c

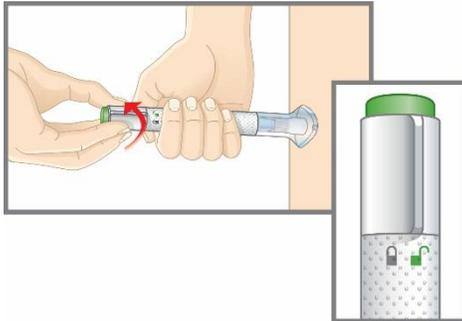
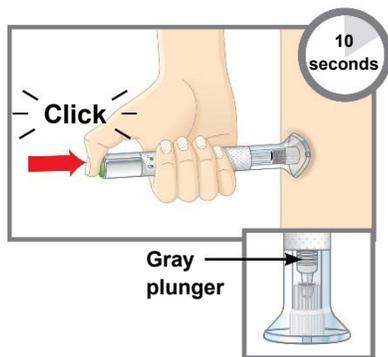


Figure E

While holding the clear base against your skin, turn the lock ring to the unlock position (see Figure E). You are now ready to inject.

Step 2d**Figure F**

Press the green injection button. There will be a loud click (see **Figure F**).

- **Keep holding the clear base** firmly against your skin.
- You will hear a **second click** in about 10 seconds after the first one. **The second click tells you that your injection is complete.**
- You will see the gray plunger at the top of the clear base.

Remove the autoinjector from your skin.

- Press a cotton ball or gauze over the injection site. **Do not** rub the injection site, as this may cause bruising. You may have slight bleeding. This is normal.

Do not put the base cap back on the autoinjector.

Step 3 Disposing of TALTZ**Step 3a****Figure G**

- Put the used TALTZ autoinjector in an FDA-cleared sharps disposal container right away after use (see **Figure G**). **Do not** throw away (dispose of) the TALTZ autoinjector 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 a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - upright and stable during use,
 - leak-resistant, and
 - 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 needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- **Do not** recycle your used sharps disposal container.

Commonly asked questions and answers.

Q. What if I see bubbles in the TALTZ autoinjector?

A. It is normal to have air bubbles in the autoinjector.

Q. What if there is a drop of liquid on the tip of the needle when I remove the base cap?

A. It is okay to see a drop of liquid on the tip of the needle.

Q. What if I unlocked the autoinjector and pressed the green injection button before I twisted off the base cap?

A. Do not remove the base cap. Dispose of the autoinjector and get a new one.

Q. Do I need to hold the injection button down until the injection is complete?

A. You do not need to hold the injection button down, but it may help you keep the autoinjector steady and firm against your skin.

Q. What if the needle did not retract after my injection or I am not sure that the autoinjector worked in the right way?

A. Do not touch the needle or replace the base cap. Store the autoinjector in a safe place (e.g., a household container as described in “**Disposing of TALTZ**”) to avoid an accidental needlestick and contact Lilly (1-800-545-5979) for instructions on how to return the autoinjector.

Q. What if I hear more than 2 clicks during my injection? Did I get my complete dose?

A. You may hear a soft click right before the second loud click. This is the normal operation of the autoinjector. Do not remove the autoinjector from your skin until you hear the second loud click.

Q. How can I tell if my injection is complete?

A. After you press the green injection button, you will hear 2 loud clicks. The second click tells you that your injection is complete. You will also see the gray plunger at the top of the clear base.

Q. What if the autoinjector is left at room temperature for longer than 30 minutes?

A. If needed, the autoinjector may be left out of the refrigerator at room temperature up to 86°F (30°C) for up to 5 days if protected from light. Throw away TALTZ if not used within the 5-day period at room temperature. See “**Storing TALTZ**” for more detail.

If you have more questions about how to use the TALTZ autoinjector:

- Call your healthcare provider
- Call Lilly at 1-800-545-5979 (1-800-Lilly-Rx)
- Visit www.taltz.com



Storing TALTZ

- Protect TALTZ from light.
- Store TALTZ in the refrigerator between 36°F to 46°F (2°C to 8°C).
 - If needed, you or a caregiver may store TALTZ at room temperature up to 86°F (30°C) for up to 5 days in the original carton to protect from light. Once TALTZ has been stored at room temperature, do not return to the refrigerator. Throw away TALTZ if it is not used within 5 days at room temperature.
 - Record the date when TALTZ is first removed from the refrigerator in the spaces provided on the carton.
 - For the 2 or 3 autoinjector pack, remove a single autoinjector at a time leaving the remaining autoinjector(s) in the original carton in the refrigerator. Ensure the unrefrigerated TALTZ is protected from light.
- Do not freeze TALTZ. Do not use if TALTZ has been frozen.
- Do not shake TALTZ.

Keep TALTZ and all medicines out of the reach of children.

Read the full Prescribing Information and Medication Guide for TALTZ inside this box to learn more about your medicine.



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Indianapolis, IN 46285, USA
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The TALTZ autoinjector meets the current dose accuracy and functional requirements of ISO 11608-1 and 11608-5.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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