TEZSPIRE® (tezepelumab-ekko) injection, for subcutaneous use

Administration Instructions for Single-Dose Pre-filled Syringe

Refer to Figure 1 to identify the pre-filled syringe components for use in the administration steps.
Do not remove the needle cover until Step 2 of these instructions when you are ready to inject TEZSPIRE. Do not touch the needle guard activation clips to prevent premature activation of the needle safety guard.

Figure 1  TEZSPIRE Pre-filled Syringe Components

<table>
<thead>
<tr>
<th>Before use</th>
<th>After use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Needle guard activation clips</td>
<td>Needle guard</td>
</tr>
<tr>
<td>Viewing window</td>
<td>Label with expiration date</td>
</tr>
<tr>
<td>Plunger head</td>
<td>Needle</td>
</tr>
<tr>
<td>Finger flange</td>
<td>Needle cover</td>
</tr>
<tr>
<td>Plunger</td>
<td>Plunger</td>
</tr>
</tbody>
</table>

1. Grasp the syringe body to remove the pre-filled syringe from its tray. Do not grab the pre-filled syringe by the plunger. The pre-filled syringe may contain small air bubbles; this is normal. Do not expel the air bubbles prior to administration.

2. Do not remove the needle cover until ready to inject. Hold the syringe body and remove the needle cover by pulling straight off. Do not hold the plunger or plunger head while removing the needle cover. You may see a drop of liquid at the end of the needle. This is normal.

3. Gently pinch the skin and administer subcutaneously at approximately 45º angle into the recommended injection site (i.e., upper arm, thigh, or abdomen).

4. Inject all of the medication by pushing in the plunger all the way until the plunger head is completely between the needle guard activation clips. This is necessary to activate the needle guard.

5. After injection, maintain pressure on the plunger head and remove the needle from the skin. Release pressure on the plunger head to allow the needle guard to cover the needle. Do not re-cap the pre-filled syringe.

6. Discard the used syringe into a sharps container.

Administration Instructions for Single-Dose Pre-filled Pen

These administration instructions are intended for healthcare providers use only. Patients and caregivers should refer to the TEZSPIRE pre-filled pen ‘Instructions for Use’ for more detailed instructions on the preparation and administration of TEZSPIRE pre-filled pen [See Instructions for Use].
Patients/caregivers may inject after proper training in subcutaneous injection technique according to the ‘Instructions for Use’, and after the healthcare provider determines it is appropriate.

Refer to Figure 2 to identify the pre-filled pen components for use in the administration steps.
Do not remove the cap until you are ready to inject TEZSPIRE.

Figure 2  TEZSPIRE Pre-filled Pen Components

<table>
<thead>
<tr>
<th>Before use</th>
<th>After use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viewing window</td>
<td>Label with expiration date</td>
</tr>
<tr>
<td>Liquid medicine</td>
<td>Cap</td>
</tr>
<tr>
<td>Orange plunger</td>
<td>Orange needle guard</td>
</tr>
</tbody>
</table>

1. Grab the middle of the pre-filled pen body to remove the pre-filled pen from its tray. The pre-filled pen may contain small air bubbles; this is normal. Do not expel the air bubbles prior to administration.

2. Do not remove the cap until ready to inject. Hold the pre-filled pen body with 1 hand and carefully pull the cap straight off with your other hand. Do not touch the needle or push the orange needle guard with your finger. Do not put the cap back on the pre-filled pen. You could cause the injection to happen too soon or damage the needle.

3. Gently pinch the skin at the injection site or give the injection without pinching the skin.

Inject TEZSPIRE by following the steps into the recommended injection site (i.e., upper arm, thigh, or abdomen).

When injecting, you will hear the first click that tells you the injection has started. Press and hold the pre-filled pen for 15 seconds until you hear the second click. Do not change the position of the pre-filled pen after the injection has started.

4. Position the pre-filled pen. Place the orange needle guard flat against the skin (90-degree angle). Make sure you can see the viewing window.

5. Press down firmly until you cannot see the orange needle guard. You will hear the first ‘click’, this tells you the injection has started. The orange plunger will move down in the viewing window during the injection.

6. Hold down firmly for about 15 seconds. You will hear a second ‘click’, this tells you the injection has finished. The orange plunger will fill the viewing window.

7. After you have completed the injection, lift the pre-filled pen straight up. The orange needle guard will slide down and lock into place over the needle.

8. Discard the used pre-filled pen into a sharps container.
INSTRUCTIONS FOR USE

TEZSPIRE® (TEZ-SPY-ER)
(tezepelumab-ekko)
injection, for subcutaneous use

Single-dose Pre-filled pen

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

Before using your TEZSPIRE pre-filled pen, your healthcare provider should show you or your caregiver how to use it the right way.

Read this Instructions for Use before you start using your TEZSPIRE pre-filled pen and each time you get a refill. There may be new information. This information should not replace talking to your healthcare provider about your medical condition and your treatment.

If you or your caregiver have any questions, talk to your healthcare provider.

Important information you need to know before injecting TEZSPIRE

Store TEZSPIRE in a refrigerator between 36°F to 46°F (2°C to 8°C) in its original carton until you are ready to use it.

TEZSPIRE may be kept at room temperature between 68°F to 77˚F (20°C to 25°C) for a maximum of 30 days.

Store TEZSPIRE in the original carton to protect it from light.

When TEZSPIRE has reached room temperature, do not put it back in the refrigerator.

Throw away (dispose of) TEZSPIRE that has been stored at room temperature for more than 30 days.

Do not use your TEZSPIRE pre-filled pen if:

- it has been frozen
- it has been dropped or damaged
- the security seal on the carton has been broken
- the expiration date (EXP) has passed

If any of the above happens, throw away the pre-filled pen in a puncture-resistant (sharps) container and use a new TEZSPIRE pre-filled pen.

Each TEZSPIRE pre-filled pen contains 1 dose of TEZSPIRE that can only be used 1 time.

TEZSPIRE is given only as an injection under the skin (subcutaneous).

Keep the TEZSPIRE pre-filled pen and all medicines out of the sight and reach of children.

Your TEZSPIRE pre-filled pen

Do not remove the cap until Step 6 of these instructions when you are ready to inject TEZSPIRE.

Preparing to inject TEZSPIRE

Step 1 – Gather supplies

- 1 TEZSPIRE pre-filled pen from the refrigerator
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 small bandage (optional)
- 1 puncture-resistant (sharps) disposal container. See Step 10 for instructions on how to throw away (dispose of) the used TEZSPIRE pre-filled pen safely.
Step 2 – Prepare to use your TEZSPIRE pre-filled pen
Let TEZSPIRE come to room temperature between 68°F to 77°F (20°C to 25°C) for about 60 minutes before giving the injection.

Keep the pre-filled pen in its original carton to protect it from light.

Do not warm the pre-filled pen in any other way. For example, do not warm it in a microwave or hot water, in direct sunlight, or near other heat sources.

Do not put TEZSPIRE back in the refrigerator after it has reached room temperature. Throw away (dispose of) TEZSPIRE that has been stored at room temperature for more than 30 days.

Do not remove the cap until Step 6.

Step 3 – Remove and check the pre-filled pen
Grab the middle of the pre-filled pen body to remove the pre-filled pen from its tray.

Check the pre-filled pen for damage. Do not use the pre-filled pen if the pre-filled pen is damaged.

Check the expiration date on the pre-filled pen. Do not use the pre-filled pen if the expiration date has passed.

Look at the liquid through the viewing window. The liquid should be clear and colorless to light yellow.

Do not inject TEZSPIRE if the liquid is cloudy, discolored, or contains large particles.

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

Injecting TEZSPIRE
Step 4 – Choose an injection site
If you are giving yourself the injection, the recommended injection site is the front of your thigh or the lower part of your stomach (abdomen). Do not inject yourself in the arm.

A caregiver may inject you in the upper arm, thigh, or abdomen.

For each injection, choose a different site that is at least 1 inch (3 cm) away from where you last injected.

Do not inject:
- into the 2-inch (5 cm) area around your belly button
- where the skin is tender, bruised, scaly or hard
- into scars or damaged skin
- through clothing

Step 5 – Wash your hands and clean the injection site
Wash your hands well with soap and water.

Clean the injection site with an alcohol wipe in a circular motion. Let it air dry.

Do not touch the cleaned area before injecting.

Do not fan or blow on the cleaned area.
Step 6 – Pull off the cap
Do not remove the cap until you are ready to inject.
Hold the pre-filled pen body with 1 hand, and carefully pull the cap straight off with your other hand.
Put the cap to the side and throw it away later.
The orange needle guard is now exposed. The orange needle guard is there to prevent you from touching the needle.
Do not touch the needle or push on the orange needle guard with your finger.
Do not put the cap back on the pre-filled pen. You could cause the injection to happen too soon or damage the needle.

Step 7 – Inject TEZSPIRE
Follow your healthcare provider’s instruction on how to inject. You can either gently pinch the skin at the injection site or give the injection without pinching the skin.
Inject TEZSPIRE by following the steps in figures a, b, c and d.
When injecting, you will hear the first click that tells you the injection has started. Press and hold the pre-filled pen for 15 seconds until you hear the second click.
Do not change the position of the pre-filled pen after the injection has started.

Position the pre-filled pen.
- Place the orange needle guard flat against your skin (90-degree angle).
- Make sure you can see the viewing window.

Press down firmly until you cannot see the orange needle guard.
- You will hear the first ‘click’, this tells you the injection has started.
- The orange plunger will move down in the viewing window during the injection.

Hold down firmly for about 15 seconds.
- You will hear a second ‘click’, this tells you the injection has finished.
- The orange plunger will fill the viewing window.

After you have completed your injection, lift the pre-filled pen straight up.
- The orange needle guard will slide down and lock into place over the needle.
Step 8 – Check the viewing window
Check the viewing window to make sure all the medicine has been injected. If the orange plunger rod does not fill the viewing window, you may not have received the full dose.

If this happens or if you have any other concerns, contact your healthcare provider.

Before injection

After injection

Step 9 – Check the injection site
There may be a small amount of blood or liquid where you injected. This is normal.

Gently hold pressure over your skin with a cotton ball or gauze until the bleeding stops.

Do not rub the injection site. If needed, cover the injection site with a small bandage.

Disposing of TEZSPIRE
Step 10 – Dispose of the used pre-filled pen safely
Each pre-filled pen contains a single dose of TEZSPIRE and cannot be used again. Do not put the cap back on the pre-filled pen.

Put your used pre-filled pen and cap in a sharps disposal container right away after use. Put other used supplies in your household trash.

Do not throw away the pre-filled pen in your household trash.

Throw away (Disposal) guidelines
If you do not have a 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 used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the area that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

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