

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **TEZSPIRE®** **Tezepelumab**

This patient medication information is written for the person who will be taking **TEZSPIRE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **TEZSPIRE**, talk to a healthcare professional.

What TEZSPIRE is used for:

Asthma

- TEZSPIRE is a prescription medicine used with other asthma medicines for the maintenance treatment of severe asthma in people 12 years of age and older whose asthma is not controlled with their current asthma medicine.
- TEZSPIRE is not used to treat sudden breathing problems.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- TEZSPIRE is used with other medicines for the maintenance treatment of severe CRSwNP in adults (18 years of age and older) whose CRSwNP is not controlled with systemic corticosteroids and/or surgery.

How TEZSPIRE works:

TEZSPIRE works by blocking the action of thymic stromal lymphopoietin (TSLP), a protein that plays a role in causing the signs and symptoms of asthma and CRSwNP.

Asthma

TEZSPIRE may reduce the number of asthma attacks you experience, improve your breathing and reduce your asthma symptoms.

CRSwNP

TEZSPIRE may reduce the size of your polyps and improve symptoms including nasal congestion and loss of smell. TEZSPIRE may also reduce the need for oral corticosteroids and surgery.

The ingredients in TEZSPIRE are:

Medicinal ingredient: tezepelumab

Non-medicinal ingredients: glacial acetic acid, L-proline, polysorbate 80, sodium hydroxide, and water for injection.

TEZSPIRE comes in the following dosage form:

Solution for injection.

Each single-use, pre-filled syringe or pre-filled pen contains 210 mg of tezepelumab in 1.91 mL of solution.

Do not use TEZSPIRE if:

- you are allergic to tezepelumab or any of the other ingredients of this medicine. Check with your healthcare professional if you think, or you are not sure, if this applies to you.

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

- have asthma that remains uncontrolled or worsens during treatment with TEZSPIRE.
- have had any symptoms of an allergic reaction. TEZSPIRE can potentially cause serious allergic reactions. Symptoms may vary, but can include swelling of your face, tongue or mouth, breathing problems, fainting, dizziness, feeling lightheaded, hives, and rash. If you notice any of these signs, speak to your healthcare professional immediately.
- have a parasitic infection or if you live in an area where parasitic infections are common or if you are travelling to such a region. TEZSPIRE may weaken your ability to fight certain types of parasitic infections.
- are pregnant, think you may be pregnant, or plan to become pregnant. Do not use TEZSPIRE unless your healthcare professional tells you to. It is not known if TEZSPIRE can harm your unborn baby.
- are breast-feeding. TEZSPIRE may pass into breast milk. Your healthcare professional will discuss with you whether you should stop treatment with TEZSPIRE while you are breast-feeding, or if you should stop breast-feeding.

Other warnings you should know about:

TEZSPIRE is not a rescue medicine and should not be used to treat a sudden asthma attack.

TEZSPIRE is not approved for use in children below the age of 12 years for the treatment of asthma.

TEZSPIRE is not approved for use in children below the age of 18 years for the treatment of CRSwNP.

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

There are no known interactions with TEZSPIRE.

Tell your healthcare professional if you have recently had or are due to have a vaccination.

Do not suddenly stop taking your asthma medicines once you have started TEZSPIRE.

These medicines (especially ones called corticosteroids) must be stopped gradually, under the direct supervision of your doctor and based on your response to TEZSPIRE.

How to take TEZSPIRE:

- Always use TEZSPIRE exactly as your healthcare professional has told you. If you or your caregiver have any questions, talk to your healthcare professional.
- TEZSPIRE is given as an injection just under the skin (subcutaneously).
- Your healthcare professional should decide if you or your caregiver should inject TEZSPIRE. Before using your TEZSPIRE pre-filled syringe or pre-filled pen, your healthcare

professional should show you or your caregiver how to use it the right way. Read the “INSTRUCTIONS FOR USE” for TEZSPIRE pre-filled syringe or pre-filled pen carefully before using TEZSPIRE and each time you get a refill. There may be new information.

- Do not share or use TEZSPIRE pre-filled syringe or pre-filled pen more than one time.
- Do not stop using TEZSPIRE without speaking to your healthcare professional first. Interrupting or stopping the treatment with TEZSPIRE may cause your symptoms to come back.

Usual dose:

Asthma: Adults and adolescents (12 years and older)

The recommended dose is 210 mg injected under your skin (subcutaneously) 1 time every 4 weeks.

CRSwNP: Adults (18 years and older)

The recommended dose is 210 mg injected under your skin (subcutaneously) 1 time every 4 weeks.

Overdose:

If you think you, or a person you are caring for, have taken too much TEZSPIRE, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you or your caregiver missed a dose, inject a dose as soon as possible. Continue your next injection on your usual injection day. If you did not notice that you have missed a dose until it is time for your next scheduled dose, then inject the next scheduled dose as planned. If you are not sure when to inject TEZSPIRE, contact your healthcare professional.

Possible side effects from using TEZSPIRE:

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

Common (These may affect **up to 1 in 10 people**):

- Sore throat (pharyngitis)
- Injection site reaction (i.e., redness, swelling, and pain)
- Joint pain (arthralgia)
- Rash

Serious side effects and what to do about them:

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
NOT KNOWN			
Allergic reactions (anaphylaxis) that may happen within hours or			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
days after the injection: swelling of your face, tongue, or mouth, breathing problems, fainting, dizziness, feeling lightheaded			

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 (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Do not use this medicine if it has been dropped or damaged, if the security seal on the carton has been broken or after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store between 2°C to 8°C (in a refrigerator) in the original package in order to protect from light. TEZSPIRE may be kept at room temperature (20°C to 25°C) in the original carton for a maximum of 30 days. Once 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 after 30 days.

Do not shake, freeze or expose to heat.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Keep out of reach and sight of children.

If you want more information about TEZSPIRE:

- 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 Drug Product Database website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4.

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INSTRUCTIONS FOR USE – PRE-FILLED SYRINGE

Pr **TEZSPIRE®**

Tezepelumab injection, Subcutaneous use Single-use, Pre-filled Syringe

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

Before using your TEZSPIRE pre-filled syringe, 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 syringe 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 2°C to 8°C in its original carton until you are ready to use it to protect it from light. TEZSPIRE may be kept at room temperature between 20°C to 25°C in the original carton for a maximum of 30 days.

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 syringe 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

Do not shake your pre-filled syringe.

Do not share, or use your pre-filled syringe more than 1 time.

Do not expose your TEZSPIRE pre-filled syringe to heat.

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

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

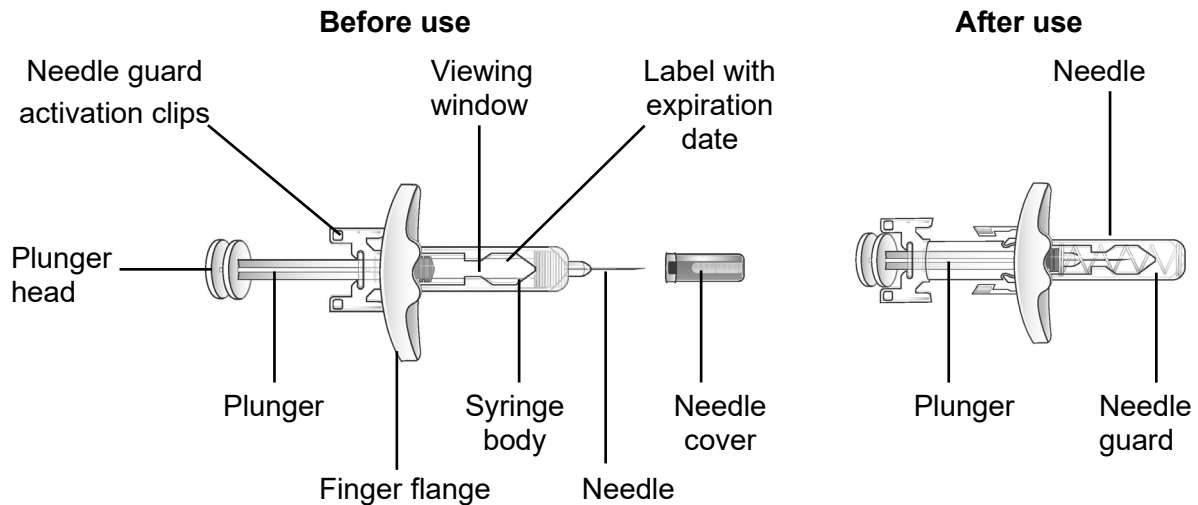
Keep TEZSPIRE pre-filled syringe and all medicines out of the sight and reach of children.

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

Your TEZSPIRE pre-filled syringe

Do not remove the needle cover until Step 7 of these instructions when you are ready to inject TEZSPIRE.

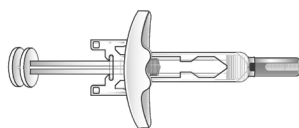
Do not touch the needle guard activation clips. This will keep you from activating the safety device (needle guard) too soon.



Preparing to inject TEZSPIRE

Step 1 – Gather supplies

- 1 TEZSPIRE pre-filled syringe 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 syringe safely.



Pre-filled syringe



Alcohol wipe



Cotton ball
or gauze



Bandage



Sharps
disposal
container

Step 2 – Prepare to use your TEZSPIRE pre-filled syringe

Let TEZSPIRE come to room temperature between 20°C to 25°C for about 60 minutes or longer (up to a maximum of 30 days) before giving the injection.

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

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

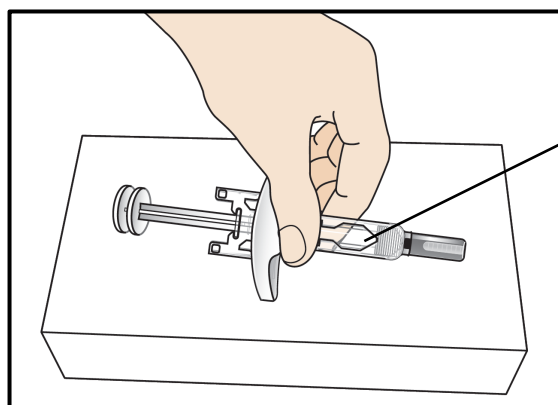
Do not put TEZSPIRE back in the refrigerator after it has reached room temperature. Throw away (dispose of) TEZSPIRE that has been stored at room temperature for more than 30 days.

Do not remove the needle cover until Step 7.



Step 3 – Remove pre-filled syringe

Grab the syringe body to remove the pre-filled syringe from its carton. **Do not** grab the pre-filled syringe by the plunger.



Syringe body

Step 4 – Check the pre-filled syringe

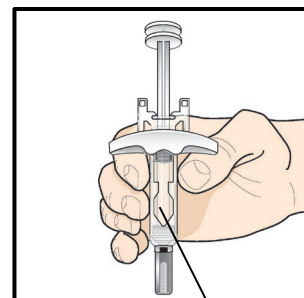
Check the pre-filled syringe for damage. **Do not** use the pre-filled syringe if the pre-filled syringe is damaged.

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

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

Do not inject TEZSPIRE if the liquid is cloudy, discoloured, 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.



Expiration date

Injecting TEZSPIRE

Step 5 – Choose an injection site

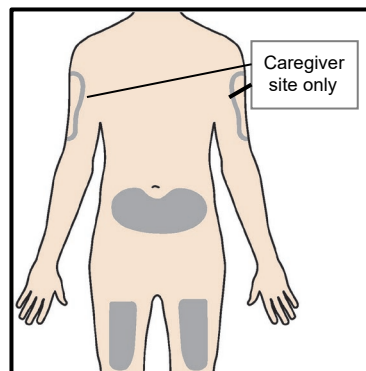
If you are giving yourself the injection, the **recommended injection site** is the front of your thigh or the lower part of your stomach (abdomen). **Do not** inject yourself in the arm.

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

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

Do not inject:

- into the 5 cm area around your belly button
- where the skin is tender, bruised, scaly or hard
- into scars or damaged skin
- through clothing



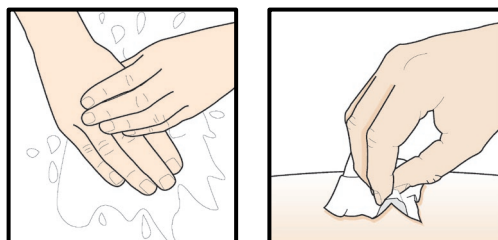
Step 6 – Wash your hands and clean the injection site

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 7 – Pull off the needle cover

Do not remove the needle cover until you are ready to inject.

Hold the syringe body with 1 hand, and carefully pull the needle cover straight off with your other hand.

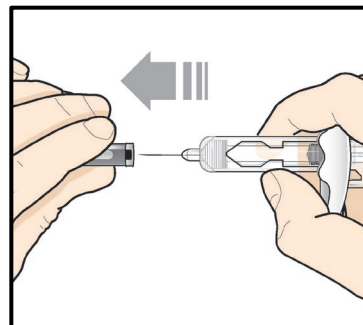
Do not hold the plunger or plunger head while removing the needle cover.

Put the needle cover to the side and throw it away later.

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.

Do not put the needle cover back on the syringe.



Step 8 – Inject TEZSPIRE

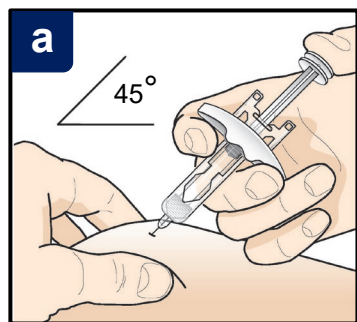
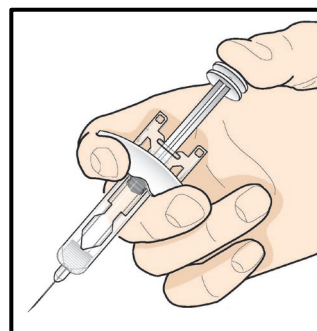
Hold the pre-filled syringe in 1 hand as shown.

Use your other hand to gently pinch and hold the area of skin where you want to inject. This will make the skin more firm.

Do not press down on the plunger head until the needle is inserted into the skin.

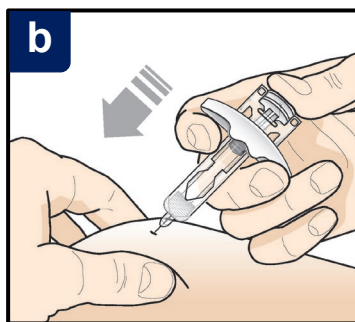
Do not pull back on the plunger head at any time.

Inject TEZSPIRE by following the steps in figures a, b and c.

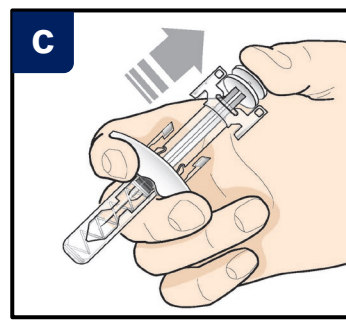


Using a 45 degree angle, fully insert the needle into the pinched skin.

Do not try to change the position of the pre-filled syringe after you insert it into the skin.



Use your thumb to push down on the plunger head. Keep pushing until it is down as far as it will go to make sure you inject all of the medicine.



Keep your thumb pressed down on the plunger head as you take the needle out of the skin.

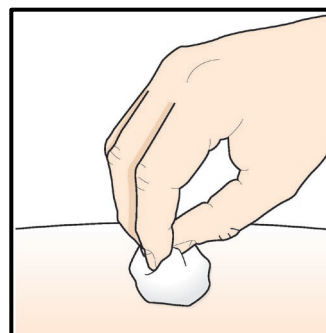
Slowly let go of the plunger until the needle guard covers the needle.

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.



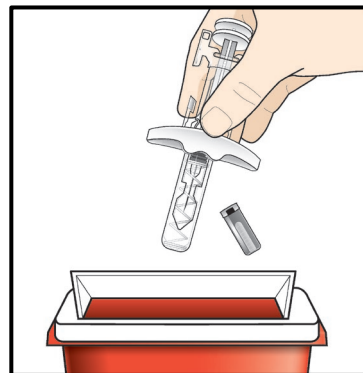
Disposing of TEZSPIRE

Step 10 – Dispose of the used pre-filled syringe safely

Each pre-filled syringe contains a single dose of TEZSPIRE and **cannot be used again**. **Do not** put the needle cover back on the pre-filled syringe.

Put your used pre-filled syringe and needle cover in a **sharps disposal container** right away after use. Put other used supplies in your household trash.

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



Disposal guidelines

Dispose of the full container as instructed by your healthcare provider or pharmacist.

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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INSTRUCTIONS FOR USE – PRE-FILLED PEN

Pr **TEZSPIRE®**

Tezepelumab injection, Subcutaneous use

Single-use, 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 2°C to 8°C in its original carton until you are ready to use it to protect it from light. TEZSPIRE may be kept at room temperature between 20°C to 25°C in the original carton for a maximum of 30 days.

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

Do not shake your pre-filled pen.

Do not share, or use your pre-filled pen more than 1 time.

Do not expose your TEZSPIRE pre-filled pen to heat.

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.

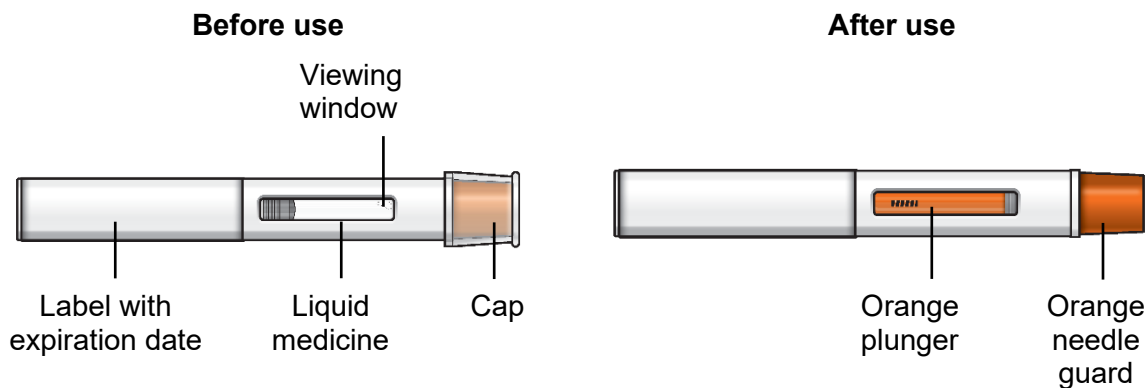
Each TEZSPIRE pre-filled pen contains 1 dose of TEZSPIRE that can only be used 1 time.

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

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

Your TEZSPIRE pre-filled pen

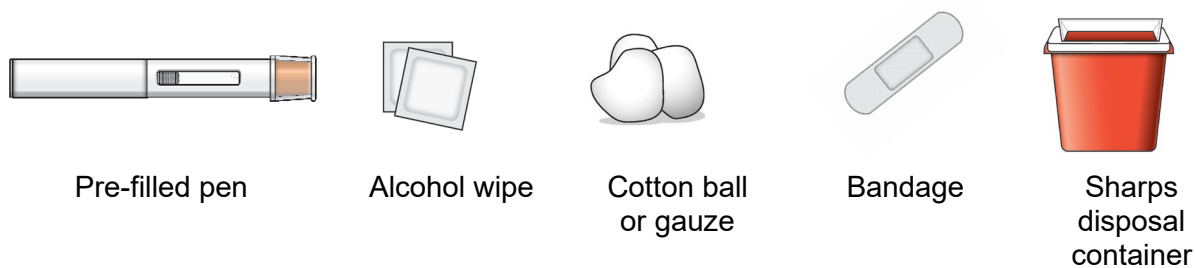
Do not remove the cap until Step 6 of these instructions when you are ready to inject TEZSPIRE.



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 20°C to 25°C for about 60 minutes or longer (up to a maximum of 30 days) 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 carton.

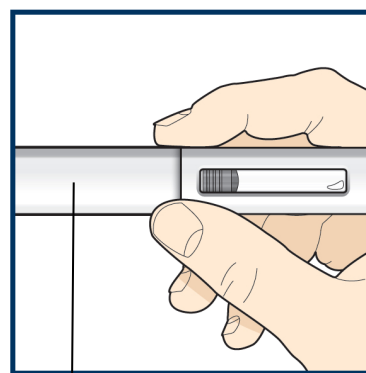
Check the pre-filled pen for damage. **Do not** use the pre-filled pen if the pre-filled pen is damaged.

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 colourless to light yellow.

Do not inject TEZSPIRE if the liquid is cloudy, discoloured, 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.



Expiration date

Injecting TEZSPIRE

Step 4 – Choose an injection site

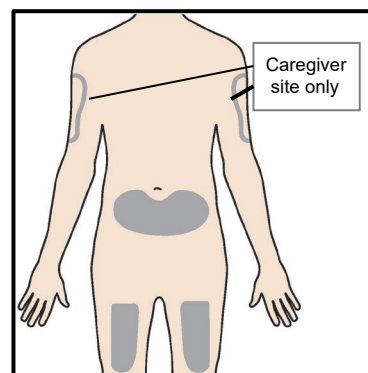
If you are giving yourself the injection, the **recommended injection site** is the front of your thigh or the lower part of your stomach (abdomen). **Do not** inject yourself in the arm.

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

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

Do not inject:

- into the 5 cm area around your belly button
- where the skin is tender, bruised, scaly or hard
- into scars or damaged skin
- through clothing



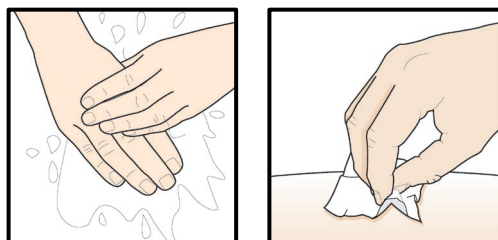
Step 5 – Wash your hands and clean the injection site

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.

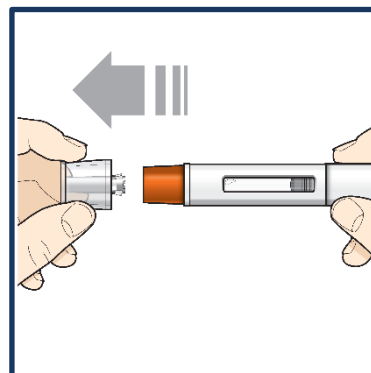
Hold the pre-filled pen body with 1 hand, and carefully pull the cap straight off with your other hand.

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.



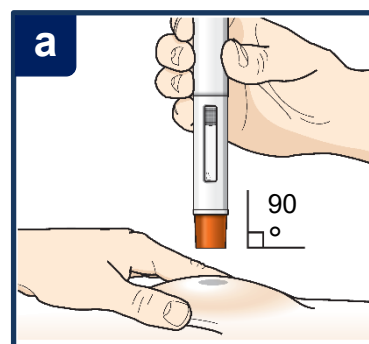
Step 7 – Inject TEZSPIRE

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**.

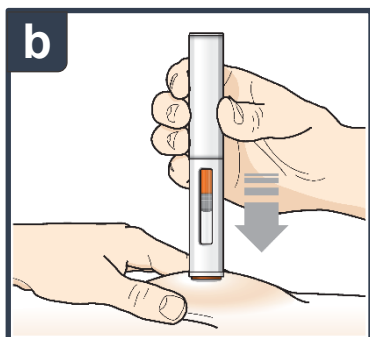
Do not change the position of the pre-filled pen after the injection has started.



Position the pre-filled pen.

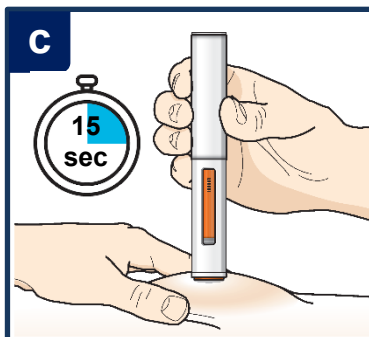
- Place the orange needle guard flat against your skin (90-degree angle).

- Make sure you can see the viewing window.



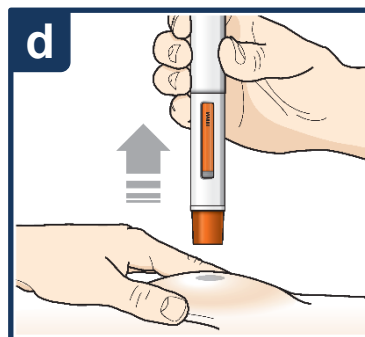
Press down firmly until you cannot see the orange needle guard.

- 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.

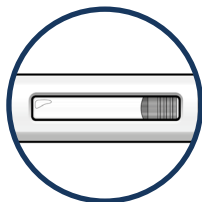
Step 8 – Check the viewing window

Check the viewing window to make sure all the medicine has been injected.

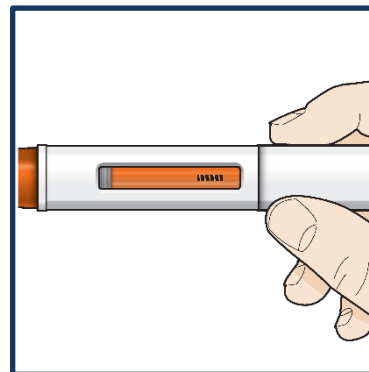
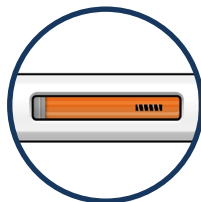
If the orange plunger rod does not fill the viewing window, you may not have received the full dose.

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

Before
injection



After
injection

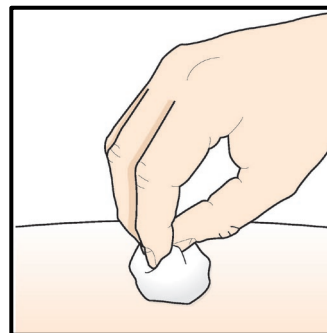


Step 9 – Check the injection site

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.



Disposal guidelines

Dispose of the full container as instructed by your healthcare provider or pharmacist.

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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