

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

**Pr FASENRA® and Pr FASENRA PEN™
benralizumab injection**

Read this carefully before you start taking **FASENRA** and each time you get an injection. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FASENRA**.

What is FASENRA used for?

FASENRA is a prescription medicine used in addition to other asthma medicines for maintenance treatment of adult patients with severe eosinophilic asthma, whose asthma is not controlled with their current asthma medicines. Severe eosinophilic asthma is a type of asthma where patients have increased eosinophils in the blood or lungs. Eosinophils are a type of white blood cell that are associated with inflammation of the airways that can cause your asthma to get worse or can increase the number of asthma attacks.

FASENRA helps reduce the number of asthma attacks that you experience.

FASENRA is not used to treat other problems caused by eosinophils. FASENRA is not used to treat sudden breathing problems.

How does FASENRA work?

FASENRA contains the active substance, benralizumab, a monoclonal antibody that works by affecting white blood cells called eosinophils. Eosinophils are a type of white blood cell that may contribute to your asthma by causing inflammation in the lungs. By attaching to the eosinophils, FASENRA reduces the number of eosinophils in the blood and lungs.

What are the ingredients in FASENRA?

Medicinal ingredient: benralizumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, α,α -trehalose dihydrate, polysorbate 20 and water.

FASENRA comes in the following dosage form:

Solution for injection.

Each single-use prefilled syringe or autoinjector contains 30 mg of benralizumab in 1 mL of solution.

Do not use FASENRA if:

You are allergic to benralizumab or any of the other ingredients of this medicine. Talk to your doctor about whether this may apply to you.

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

- have any symptoms of an allergic reaction, including to other medicines of this type

(monoclonal antibodies) as they can cause severe allergic reactions when injected into the body (see **What are possible side effects from using FASENRA?**). Serious allergic reactions have occurred in patients receiving FASENRA.

- 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. FASENRA may weaken your ability to fight certain types of parasitic infections. Parasitic infections should be treated prior to starting treatment with FASENRA.
- feel that your asthma symptoms get worse when being treated with FASENRA.

Other warnings you should know about:

Effects when treatment with FASENRA is stopped

Do not stop receiving injections of FASENRA unless advised by your doctor. Interrupting or stopping the treatment with FASENRA may cause your asthma symptoms to become worse or cause an asthma attack.

Other medicines for asthma

Do not suddenly stop taking your other asthma medications once you have started FASENRA. These medicines (especially *corticosteroids*) must be stopped gradually, under the direct supervision of your doctor.

Pregnancy and breastfeeding

- If you are pregnant, think you may be pregnant, or are planning to become pregnant, tell your doctor before using this medicine. It is preferable to avoid the use of FASENRA during pregnancy. It is not known if FASENRA may harm your unborn baby. There is a pregnancy registry for women who are treated with FASENRA while pregnant. The purpose of the registry is to collect information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and register by calling 1-877-311-8972 or by visiting <http://mothertobaby.org/ongoing-study/fasenra/>.
- If you become pregnant while being treated with FASENRA or within 4 months of stopping treatment with FASENRA, tell your doctor right away.
- It is not known whether the ingredients of FASENRA can pass into breast milk. If you are breastfeeding or plan to breastfeed, you must tell your doctor before being treated with FASENRA.

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

How to take FASENRA:

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

FASENRA is given as an injection just under the skin (subcutaneously).

You and your doctor should decide if you should inject FASENRA yourself.

You or your caregiver should receive training on the right way to prepare and inject FASENRA. Read the INSTRUCTIONS FOR USE carefully before using FASENRA. See INSTRUCTIONS FOR USE of FASENRA prefilled syringe or INSTRUCTIONS FOR USE of FASENRA

autoinjector (FASENRA PEN).

Usual dose:

The recommended dose is 30 mg every 4 weeks for the first 3 injections, and then every 8 weeks thereafter.

Overdose:

If you think you have taken too much FASENRA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If a dose of FASENRA is missed, contact your healthcare professional as soon as possible.

What are possible side effects from using FASENRA?

FASENRA can cause side effects, although not everybody will get them.

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

Common side effects (may affect up to 1 in 10 people):

Allergic Reactions

Patients receiving FASENRA may have allergic reactions. These reactions may occur within minutes to hours after an injection, but sometimes symptoms can start several days later.

Symptoms can include:

- swelling of your face, eyelids, lips, tongue, or mouth
- difficulty breathing, very wheezy, cough, chest tightness
- fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)
- hives
- rash

Seek medication attention immediately if you think you may be having a reaction.

Other common side effects that can occur with FASENRA include:

- headache
- sore throat
- fever
- injection site reactions (e.g., pain, redness, itching, swelling near where the injection was given)

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](https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada/adverse-reactionreporting.html) (<https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada/adverse-reactionreporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date that is stated on the label. The expiry date refers to the last day of the stated month.
- Store in the original package to protect from light.
- Store in a refrigerator (2°C to 8°C).
- FASENRA may be kept at room temperature up to 25°C for a maximum of 14 days. After removal from the refrigerator, FASENRA must be used within 14 days or discarded.
- Do not shake, freeze or expose to heat.

If you want more information about FASENRA:

- 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 website](#); the manufacturer's website www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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INSTRUCTIONS FOR USE – PREFILLED SYRINGE

Pr FASENRA®
benralizumab injection
Single Use Prefilled Syringe

Before using your FASENRA prefilled syringe, your healthcare professional should show you or your caregiver how to use it correctly.

Read this Instructions for Use before you start using your FASENRA prefilled syringe and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

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

Important information

Store FASENRA in a refrigerator between 2°C to 8°C in its carton until you are ready to use it. FASENRA may be kept at room temperature up to 25°C for a maximum of 14 days. After removal from the refrigerator, FASENRA must be used within 14 days or discarded.

Do not use your FASENRA prefilled syringe if:

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

Do not:

- shake your prefilled syringe
- share or re-use your prefilled syringe

If any of the above happens, throw away the syringe in a puncture-resistant sharps container and use a new prefilled syringe.

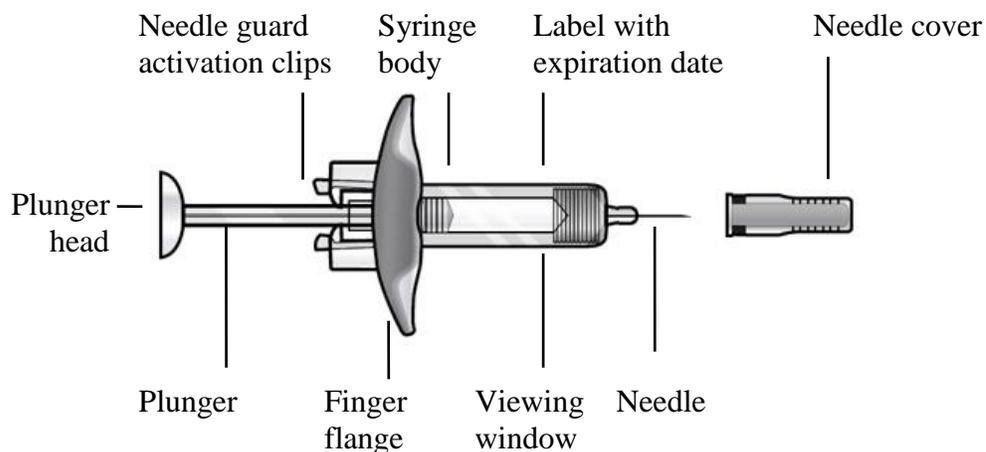
Each FASENRA prefilled syringe contains 1 dose of FASENRA that is for one-time use only.

Keep FASENRA and all medicines out of the sight and reach of children.

Your FASENRA prefilled syringe

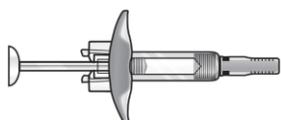
Do not remove the needle cover until you have reached Step 6 of these instructions and are ready to inject FASENRA.

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



Step 1 - Gather Supplies

- 1 FASENRA prefilled syringe from the refrigerator
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 puncture-resistant sharps container.
(See Step 9 - Dispose the used prefilled syringe)



Prefilled syringe



Alcohol wipe



Cotton ball or gauze



Sharps container

Step 2 - Prepare to use your prefilled syringe

Check the expiry date (EXP). Do not use if the expiry date has passed.

Let FASENRA warm up at room temperature 20°C to 25°C for about 30 minutes before giving the injection.

Do not warm the prefilled syringe in any other way. For example, do not warm it in a microwave or hot water, or put it near other heat sources.

Use FASENRA within 14 days of removing from the refrigerator.



Step 3 - Check the liquid

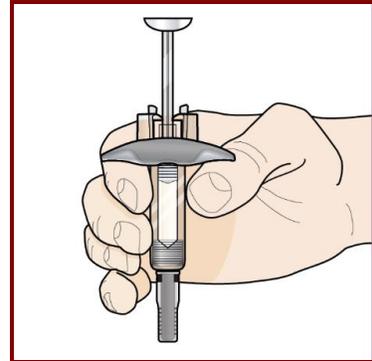
Open the carton. Peel off the entire lid from the plastic tray.

Grasp the syringe body (not the plunger) to remove the prefilled syringe from its tray.

Look at the liquid through the viewing window. The liquid should be clear and colourless to yellow. It may contain small white particles.

Do not inject FASENRA if the liquid is cloudy, discoloured, or contains large particles.

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



Step 4 - Choose the injection site

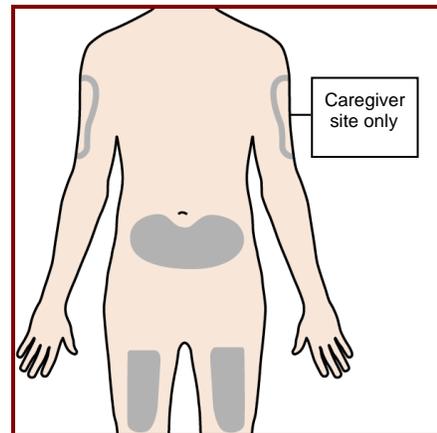
The recommended injection site is the front of your thigh. You may also use the lower part of your abdomen.

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

A caregiver may inject you in the upper-arm, thigh, or abdomen. **Do not** try to inject yourself in the arm.

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



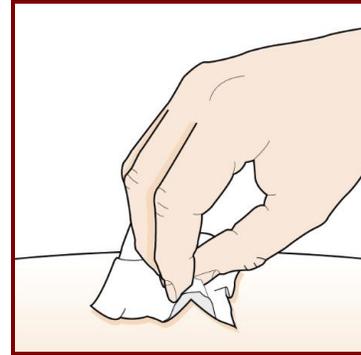
Step 5 - Prepare the injection site

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 needle cover

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.

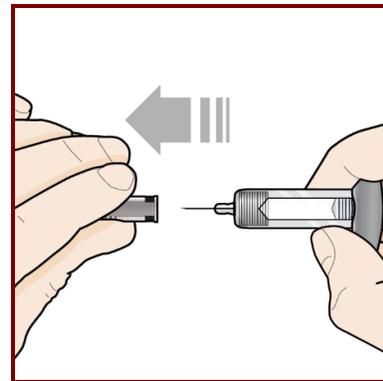
Put the needle cover aside to throw away later.

You may see a drop of liquid at the end of the needle. This is normal.

Do not use the syringe if it is dropped without the needle cover in place or if the needle is damaged or dirty.

Do not touch the needle, or let it touch any surface.

Go straight on to the next steps, without delay.



Step 7 - Inject FASENRA

Follow your healthcare professional's instructions on how to inject.

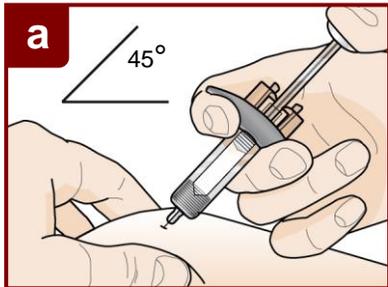
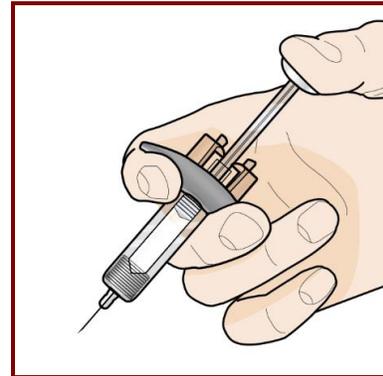
Hold the prefilled syringe in 1 hand as shown.

Use your other hand to gently pinch and hold the area of skin where you want to inject. This creates a firmer surface.

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

Do not pull back on the plunger at any time.

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



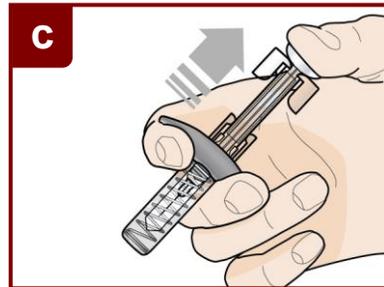
Use a quick, dart-like motion to insert the needle into the pinched skin.

Insert the needle at an angle of 45 degrees.



Use your thumb to push down on the plunger head.

Keep pushing until it is down as far as it will go. This is to make sure you inject all of the medication.



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

Slowly ease up on the plunger until the needle guard covers the needle.

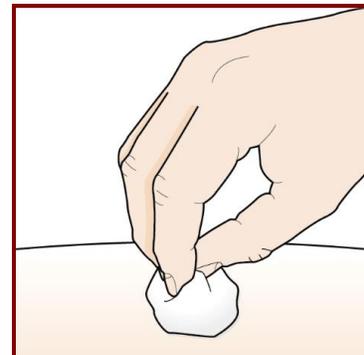
Step 8 - Check the injection site

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.



Step 9 - Dispose the used prefilled syringe

- Each prefilled syringe contains a single dose of FASENRA and **cannot be re-used**.
- Put your used prefilled syringe in a puncture-resistant **sharps container** right away after use.

Do not throw away the prefilled syringe in your household waste.

Do not re-cap the prefilled syringe.

Throw away the cap and other used supplies in your household waste.

Disposal guidelines

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

Do not dispose of your used sharps container in your household waste.

Do not recycle your used sharps container.

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INSTRUCTIONS FOR USE - AUTOINJECTOR

Pr **FASENRA PEN™**
benralizumab injection
Single Use Autoinjector

Before using your FASENRA PEN, your healthcare professional should show you or your caregiver how to use it correctly.

Read this Instructions for Use before you start using your FASENRA PEN and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

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

Important information

Store FASENRA in a refrigerator between 2°C to 8°C in its carton until you are ready to use it. FASENRA may be kept at room temperature up to 25°C for a maximum of 14 days. After removal from the refrigerator, FASENRA must be used within 14 days or discarded.

Do not use your FASENRA PEN if:

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

Do not:

- shake your FASENRA PEN
- share or re-use your FASENRA PEN

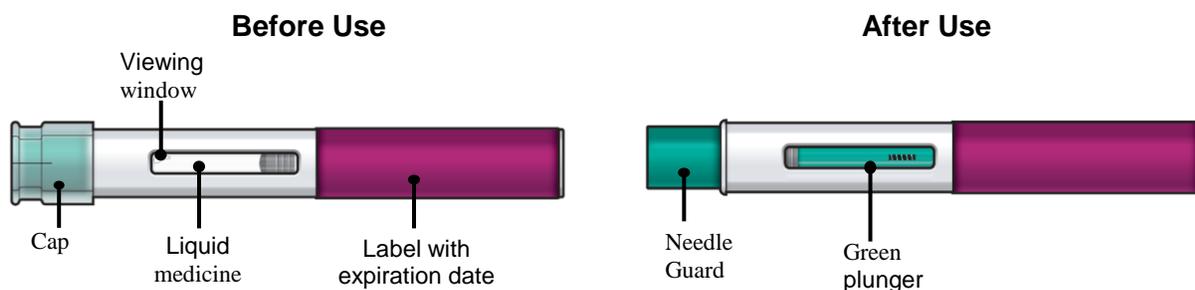
If any of the above happens, throw away the FASENRA PEN in a puncture-resistant sharps container and use a new FASENRA PEN.

Each FASENRA PEN contains 1 dose of FASENRA that is for one-time use only.

Keep FASENRA and all medicines out of the sight and reach of children.

Your FASENRA PEN

Do not remove the needle cover until you have reached Step 6 of these instructions and are ready to inject FASENRA.



Step 1 - Gather Supplies

- 1 FASENRA PEN from the refrigerator
- 1 alcohol wipe
- 1 cotton ball or gauze
- 1 puncture-resistant sharps container.
(See Step 10 - Dispose the used FASENRA PEN safely)



FASENRA PEN



Alcohol wipe



Cotton ball or gauze



Sharps container

Step 2 - Prepare to use your FASENRA PEN

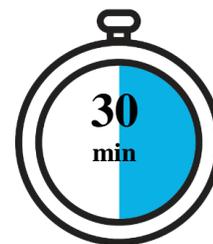
Check the expiry date (EXP). Do not use if the expiry date has passed.

Let FASENRA warm up at room temperature 20°C to 25°C for about 30 minutes before giving the injection.

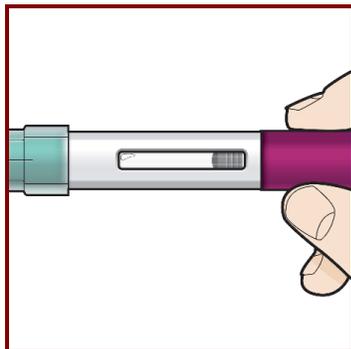
Do not warm the FASENRA PEN in any other way. For example, do not warm it in a microwave or hot water, or put it near other heat sources.

Use FASENRA within 14 days of removing from the refrigerator.

Do not remove the cap until you have reached Step 6.



Step 3 - Check the liquid

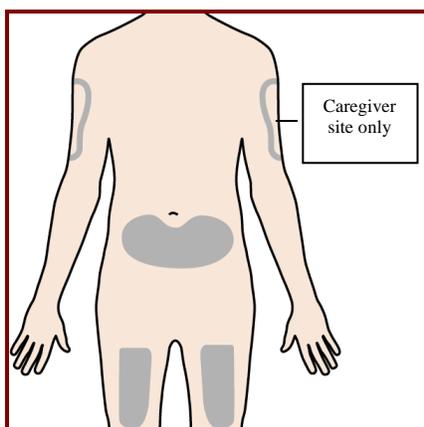


Look at the liquid in the FASENRA PEN through the viewing window. The liquid should be clear and colourless to yellow. It may contain small white particles.

Do not inject FASENRA if the liquid is cloudy, discoloured, or contains large particles.

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

Step 4 - Choose the injection site



The recommended injection site is the front of your thigh. You may also use the lower part of your abdomen.

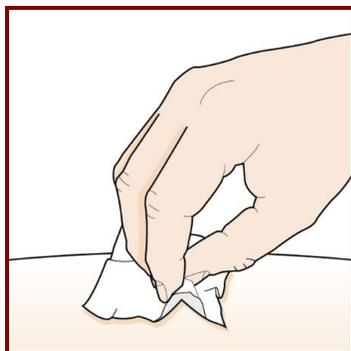
Do not inject:

- 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

A caregiver may inject you in the upper-arm, thigh, or abdomen. **Do not** try to inject yourself in the arm.

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

Step 5 - Prepare the injection site



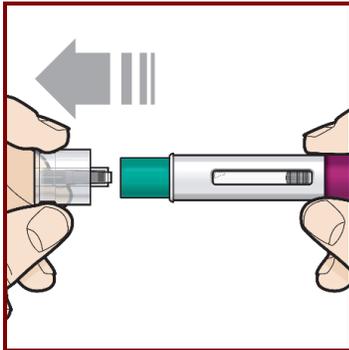
Wash your hands well with soap and water.

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



Hold the FASENRA PEN with 1 hand. Carefully pull the cap straight off with your other hand.

Put the cap aside to throw away later.

The green needle guard is now exposed. It is there to prevent you from touching the needle.

Do not try to touch the needle or push on the needle guard with your finger.

Do not try to put the cap back on the FASENRA PEN. You could cause the injection to happen too soon or damage the needle.

Complete the following steps right away after removing the cap.

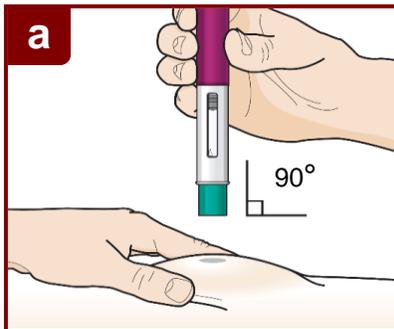
Step 7 - Inject FASENRA

Follow your healthcare professional's instructions on how to inject. You can either gently pinch at the injection site or give the injection without pinching the skin.

Inject FASENRA by following the steps in figures **a**, **b**, **c** and **d**.

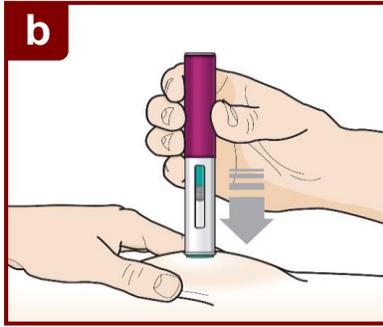
Hold the FASENRA PEN in place for the entire injection.

Do not change the position of the FASENRA PEN after the injection has started.



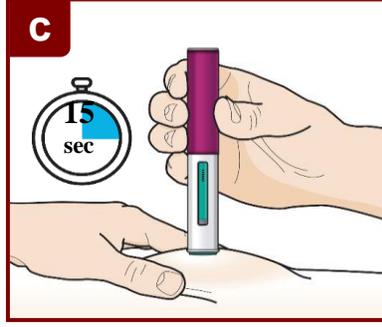
Position the FASENRA PEN at the injection site

Place the needle guard of the FASENRA PEN flat against your skin (90-degree angle). Make sure you can see the viewing window.



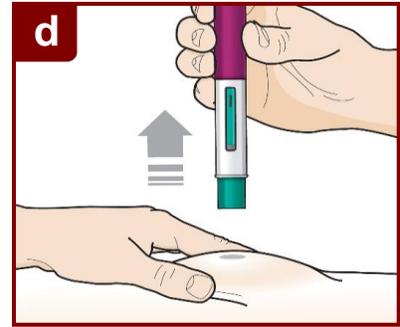
Press down firmly.

You will hear a click. A ‘click’ tells you the injection has started. The green plunger will move down in the viewing window during the injection.



Hold down firmly for 15 seconds.

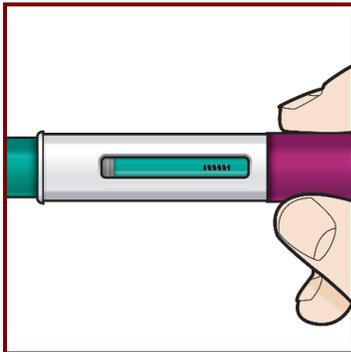
You will hear a second ‘click’. The second click tells you the injection has finished. The green plunger will fill the viewing window.



Lift the FASENRA PEN straight up.

The needle guard will slide down and lock into place over the needle.

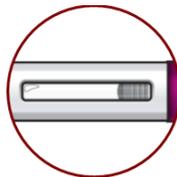
Step 8 - Check the viewing window



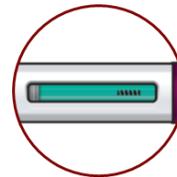
Check the viewing window to make sure all the liquid has been injected.

If the green plunger does not fill the viewing window, you may not have received the full dose. If this happens or if you have any other concerns, call your healthcare professional.

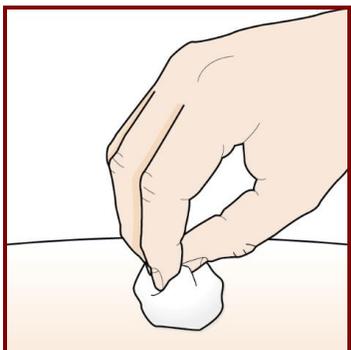
Before Injection



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.

Step 10 - Dispose of the used FASENRA PEN safely



- Each FASENRA PEN contains a single dose of FASENRA and **cannot be re-used**.
- Put your used FASENRA PEN in a puncture-resistant **sharps container** right away after use.

Do not throw away the FASENRA PEN in your household waste.

Throw away the cap and other used supplies in your household waste.

Disposal guidelines

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

Do not dispose of your used sharps container in your household waste.

Do not recycle your used sharps container.

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