Package leaflet: Information for the user

WEZENLA 45 mg solution for injection in pre-filled syringe
WEZENLA 90 mg solution for injection in pre-filled syringe
ustekinumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give WEZENLA to a child, please read this information carefully.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What WEZENLA is and what it is used for
2. What you need to know before you use WEZENLA
3. How to use WEZENLA
4. Possible side effects
5. How to store WEZENLA
6. Contents of the pack and other information

1. What WEZENLA is and what it is used for

What WEZENLA is
WEZENLA contains the active substance ‘ustekinumab’, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

WEZENLA belongs to a group of medicines called ‘immunosuppressants’. These medicines work by weakening part of the immune system.

What WEZENLA is used for
WEZENLA is used to treat the following inflammatory diseases:
- Plaque psoriasis - in adults and children aged 6 years and older
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults and children who weigh at least 40 kg
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis
Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails. WEZENLA will reduce the inflammation and other signs of the disease.

WEZENLA is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

WEZENLA is used in children and adolescents aged 6 years and older with moderate to severe plaque psoriasis who are unable to tolerate phototherapy or other systemic therapies or where these treatments did not work.

Psoriatic arthritis
Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given WEZENLA to:
- Reduce the signs and symptoms of your disease.
- Improve your physical function.
- Slow down the damage to your joints.

Crohn's disease
Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given WEZENLA to reduce the signs and symptoms of your disease.

Ulcerative colitis
Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given WEZENLA to reduce the signs and symptoms of your disease.

2. What you need to know before you use WEZENLA

Do not use WEZENLA
- **If you are allergic to ustekinumab** or any of the other ingredients of this medicine (listed in section 6).
- **If you have an active infection** which your doctor thinks is important.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using WEZENLA.

Warnings and precautions
Talk to your doctor or pharmacist before using WEZENLA. Your doctor will check how well you are before each treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have WEZENLA. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects
WEZENLA can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking WEZENLA. See 'Serious side effects' in section 4 for a full list of these side effects.

Before you use WEZENLA tell your doctor:
- **If you ever had an allergic reaction to ustekinumab**. Ask your doctor if you are not sure.
- **If you have ever had any type of cancer** – this is because immunosuppressants like WEZENLA weaken part of the immune system. This may increase the risk of cancer.
- **If you have been treated for psoriasis with other biologic medicines (a medicine produced from a biological source and usually given by injection)** – the risk of cancer may be higher.
- **If you have or have had a recent infection.**

- **If you have any new or changing lesions** within psoriasis areas or on normal skin.
- **If you are having any other treatment for psoriasis and/or psoriatic arthritis** – such as another immunosuppressant or phototherapy (when your body is treated with a type of ultraviolet (UV) light). These treatments may also weaken part of the immune system. Using these therapies together with WEZENLA has not been studied. However, it is possible it may increase the chance of diseases related to a weaker immune system.
- **If you are having or have ever had injections to treat allergies** – it is not known if WEZENLA may affect these.
- **If you are 65 years of age or over** – you may be more likely to get infections.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using WEZENLA.

Some patients have experienced lupus-like reactions including skin lupus or lupus-like syndrome during treatment with ustekinumab. Talk to your doctor right away if you experience a red, raised, scaly rash sometimes with a darker border, in areas of the skin that are exposed to the sun or with joint pains.

Heart attack and strokes
Heart attack and strokes have been observed in a study in patients with psoriasis treated with ustekinumab. Your doctor will regularly check your risk factors for heart disease and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or abnormal sensation on one side of your body, facial droop, or speech or visual abnormalities.

Children and adolescents
WEZENLA is not recommended for use in children with psoriasis under 6 years of age, children with Crohn's disease who weigh less than 40 kg or for use in children under 18 years of age with psoriatic arthritis or ulcerative colitis because it has not been studied in this age group.

Other medicines, vaccines and WEZENLA
Tell your doctor or pharmacist:
- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using WEZENLA.
- If you received WEZENLA while pregnant, tell your baby's doctor about your WEZENLA treatment before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis). Live vaccines are not recommended for your baby in the first twelve months after birth if you received WEZENLA during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- A higher risk of birth defects has not been seen in babies exposed to Ustekinumab in the womb. However, there is limited experience with Ustekinumab in pregnant women. It is therefore preferable to avoid the use of WEZENLA in pregnancy.
- If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using WEZENLA and for at least 15 weeks after the last WEZENLA treatment.
- WEZENLA can pass across the placenta to the unborn baby. If you received WEZENLA during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals if you received WEZENLA during your pregnancy before the baby receives any vaccine. Live vaccines such as the BCG vaccine (used to prevent tuberculosis) are not recommended for your

baby in the first twelve months after birth if you received WEZENLA during the pregnancy unless your baby's doctor recommends otherwise.
- Ustekinumab may pass into breast milk in very small amounts. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you should breast-feed or use WEZENLA - do not do both.

Driving and using machines
WEZENLA has no or negligible influence on the ability to drive and use machines.

WEZENLA contains polysorbate 80
WEZENLA contains 0.02 mg (45 mg/0.5 mL) or 0.04 mg (90 mg/1.0 mL) of polysorbate 80 (E 433) in each dosage unit which is equivalent to 0.04 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use WEZENLA

WEZENLA is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which WEZENLA is intended.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

How much WEZENLA is given
Your doctor will decide how much WEZENLA you need to use and for how long.

Adults aged 18 years or older
Psoriasis or Psoriatic Arthritis
- The recommended starting dose is 45 mg WEZENLA. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or ulcerative colitis
- During treatment, the first dose of approximately 6 mg/kg WEZENLA will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg WEZENLA after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg WEZENLA may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

Children and adolescents aged 6 years or older
Psoriasis
- The doctor will work out the right dose for you, including the amount (volume) of WEZENLA to be injected to give the right dose. The right dose for you will depend on your body weight at the time each dose is given.
- A 45 mg vial is available for children who need to receive less than the full 45 mg dose.
- If you weigh less than 60 kg, the recommended dose is 0.75 mg of WEZENLA per kg body weight.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg WEZENLA.
- If you weigh more than 100 kg, the recommended dose is 90 mg WEZENLA.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

Children who weigh at least 40 kg
Crohn's disease

- During treatment, the first dose of approximately 6 mg/kg WEZENLA will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg WEZENLA after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg WEZENLA may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

How WEZENLA is given
- WEZENLA is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject WEZENLA.
- However, you and your doctor may decide that you may inject WEZENLA yourself. In this case you will get training on how to inject WEZENLA yourself.
- For instructions on how to inject WEZENLA, see 'Instructions for use' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more WEZENLA than you should
If you have used or been given too much WEZENLA, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use WEZENLA
If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using WEZENLA
It is not dangerous to stop using WEZENLA. However, if you stop, your symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Some patients may have serious side effects that may need urgent treatment.

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs.
- Serious allergic reactions ('anaphylaxis') are rare in people taking ustekinumab (may affect up to 1 in 1,000 people). Signs include:
  - difficulty breathing or swallowing
  - low blood pressure, which can cause dizziness or light-headedness
  - swelling of the face, lips, mouth or throat.
- Common signs of an allergic reaction include skin rash and hives (these may affect up to 1 in 100 people).

In rare cases, allergic lung reactions and lung inflammation have been reported in patients who receive ustekinumab. Tell your doctor right away if you develop symptoms such as cough, shortness of breath, and fever.

If you have a serious allergic reaction, your doctor may decide that you should not use WEZENLA again.

Infections – these may need urgent treatment. Tell your doctor straight away if you notice any of the following signs.
- Infections of the nose or throat and common cold are common (may affect up to 1 in 10 people).

- Infections of the chest are uncommon (may affect up to 1 in 100 people).
- Inflammation of tissue under the skin ('cellulitis') is uncommon (may affect up to 1 in 100 people).
- Shingles (a type of painful rash with blisters) are uncommon (may affect up to 1 in 100 people).

WEZENLA may make you less able to fight infections. Some infections could become serious and may include infections caused by viruses, fungi, bacteria (including tuberculosis), or parasites, including infections that mainly occur in people with a weakened immune system (opportunistic infections). Opportunistic infections of the brain (encephalitis, meningitis), lungs, and eye have been reported in patients receiving treatment with ustekinumab.

You must look out for signs of infection while you are using WEZENLA. These include:
- fever, flu-like symptoms, night sweats, weight loss
- feeling tired or short of breath; cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning when passing water
- diarrhoea
- visual disturbance or vision loss
- headache, neck stiffness, light sensitivity, nausea or confusion.

Tell your doctor straight away if you notice any of these signs of infection. These may be signs of infections such as chest infections, skin infections, shingles or opportunistic infections that could have serious complications. Tell your doctor if you have any kind of infection that will not go away or keeps coming back. Your doctor may decide that you should not use WEZENLA until the infection goes away. Also tell your doctor if you have any open cuts or sores as they might get infected.

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should tell your doctor straight away if you notice any of these signs.

Other side effects

Common side effects (may affect up to 1 in 10 people):
- Diarrhoea
- Nausea
- Vomiting
- Feeling tired
- Feeling dizzy
- Headache
- Itching ('pruritus')
- Back, muscle or joint pain
- Sore throat
- Redness and pain where the injection is given
- Sinus infection

Uncommon side effects (may affect up to 1 in 100 people):
- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked or stuffy nose
- Bleeding, bruising, hardness, swelling and itching where the injection is given
- Feeling weak
- Drooping eyelid and sagging muscles on one side of the face ('facial palsy' or 'Bell's palsy'), which is usually temporary

- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1,000 people):
- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10,000 people):
- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid)
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store WEZENLA

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.
- If needed, individual WEZENLA pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the discard date. The discard date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake the WEZENLA pre-filled syringes. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:
- After the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see foreign particles floating in it (see section 6 'What WEZENLA looks like and contents of the pack').
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.

WEZENLA is for single use only. Any unused product remaining in the syringe should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What WEZENLA contains

- The active substance is ustekinumab. Each pre-filled syringe contains 45 mg ustekinumab in 0.5 mL or 90 mg ustekinumab in 1 mL.
- The other ingredients are L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80 (E 433), sucrose and water for injections.

What WEZENLA looks like and contents of the pack

WEZENLA is a clear to opalescent, colourless to light yellow solution for injection. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled syringe. Each pre-filled syringe contains 45 mg ustekinumab in 0.5 mL or 90 mg ustekinumab in 1 mL of solution for injection.

Marketing Authorisation Holder

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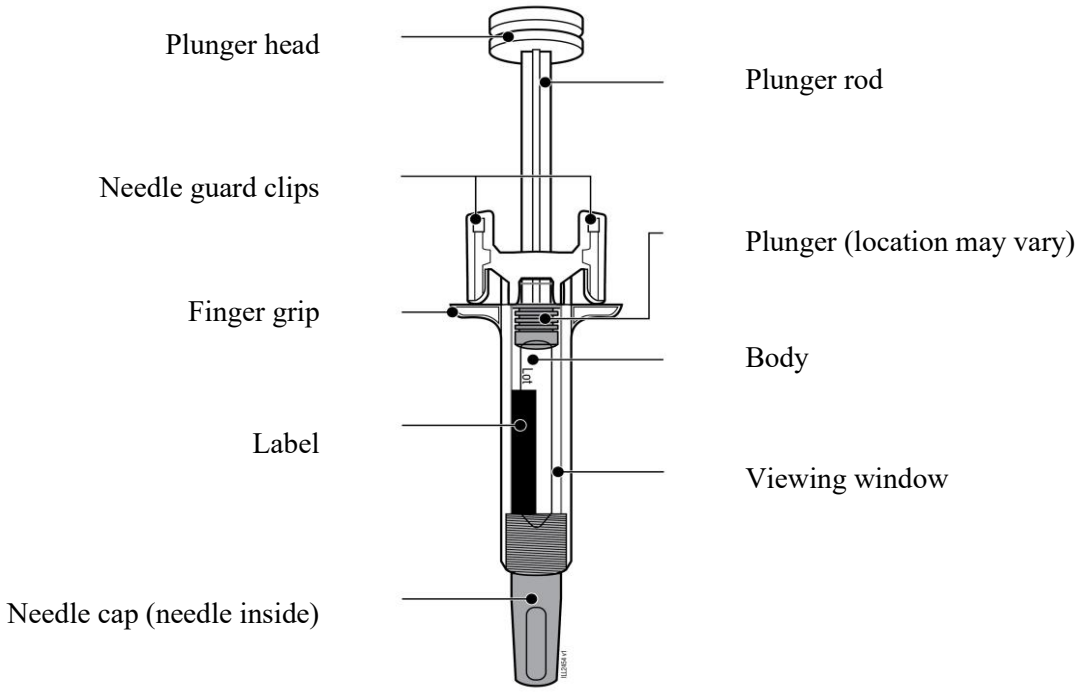
This leaflet was last revised in June 2026.

INSTRUCTIONS FOR USE

This Instructions for Use contains information on how to inject WEZENLA with a pre-filled syringe. This pre-filled syringe delivers WEZENLA with an under-the-skin (subcutaneous) injection. See Package Leaflet for medicine information.

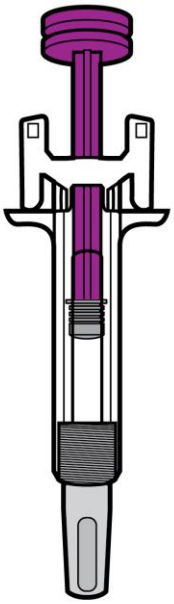
Getting to know your pre-filled syringe



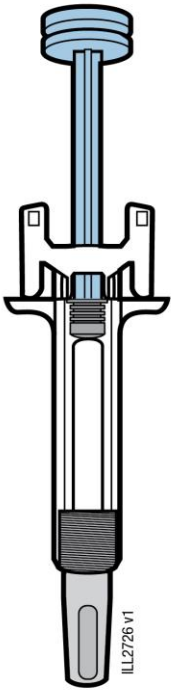
1 Important information you need to know before injecting WEZENLA

Dosing:

- WEZENLA comes in two different doses: 45 mg/0.5 mL and 90 mg/1.0 mL. Check your prescription to make sure you have the correct dose.
- The look of the pre-filled syringe will be different for each dose. The amount of medicine in the pre-filled syringe will also be different for each dose.
- For example, it's okay for the 45 mg/0.5 mL dose to have a small amount of medicine and the 90 mg/1.0 mL to have a large amount of medicine. Check the illustrations below to see what your dose looks like in the pre-filled syringe.



45 mg/0.5 mL



90 mg/1.0 mL

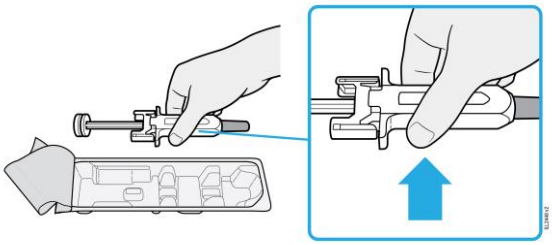
Using your WEZENLA pre-filled syringe:

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Children 12 years of age and older with psoriasis who weigh 60 kg or more may use a pre-filled syringe under supervision of a parent or caregiver.
- **Do not** use the pre-filled syringe if the carton is damaged or seal is broken.
- **Do not** use the pre-filled syringe after the expiry date on the label.
- **Do not** shake the pre-filled syringe.
- **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.
- **Do not** use the pre-filled syringe if it has been frozen.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Part of the pre-filled syringe may be broken even if you cannot see the break. If available, use a new pre-filled syringe and call your doctor or healthcare provider.

Important: Keep the pre-filled syringe and sharps disposal container out of the sight and reach of children.

2 Preparing to inject WEZENLA

2a Grasp the pre-filled syringe by the body and remove from carton.



- **Do not** grab the plunger rod, finger grip or the needle cap.
- **Do not** grab the needle guard clips.
- Remove the number of pre-filled syringes you need for your injection.
- Put any unused pre-filled syringes back into the refrigerator.

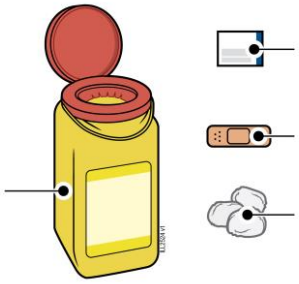
2b Wait 30 minutes for the pre-filled syringe to reach room temperature.

WAIT
30
minutes

- Let the pre-filled syringe warm up naturally.
- **Do not** heat with hot water, a microwave or direct sunlight.
- **Do not** shake the pre-filled syringe at any time.
- Using the pre-filled syringe at room temperature allows for a more comfortable injection.

2c Gather and place the items for your injection on a clean, well-lit surface.

Sharps disposal container



Alcohol wipe

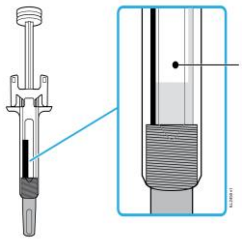
Plaster

Cotton ball or gauze pad

- WEZENLA pre-filled syringe (room temperature)
- Sharps disposal container
- Alcohol wipe
- Plaster
- Cotton ball or gauze pad

3 Getting ready for your injection

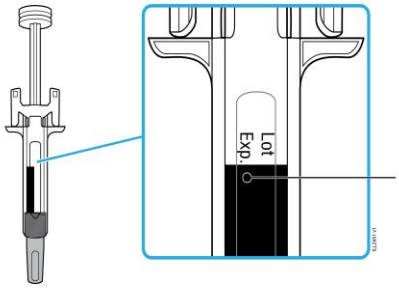
3a Inspect the medicine. It should be clear to opalescent, colourless to light yellow solution.



Medicine

- It is okay to see air bubbles in the pre-filled syringe.
- **Do not** use if the medicine is frozen, cloudy, discoloured or has foreign particles floating in it.

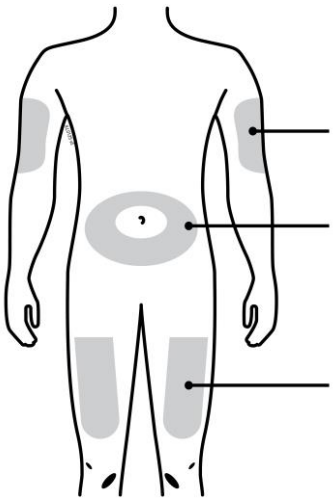
3b Check the expiry date (EXP) and inspect the pre-filled syringe.



Expiry date

- **Do not** use if the expiry date has passed.
- **Do not** use the pre-filled syringe if:
  - The cap is missing or loose.
  - It has cracks or broken parts.
  - It has been dropped on a hard surface.
- Make sure you have the correct medicine and dose.

3c Inject in one of these locations.



Upper arm

Belly

Thigh

- Inject in your thigh or belly (except 5 cm around your belly button).
- Choose a different site for each injection.

- Someone else can inject in your thigh, belly or back of the upper arm.

Important: Avoid areas with scars, stretch marks or where skin is tender, bruised, red, or hard. If possible, do not use areas of skin that show signs of psoriasis.

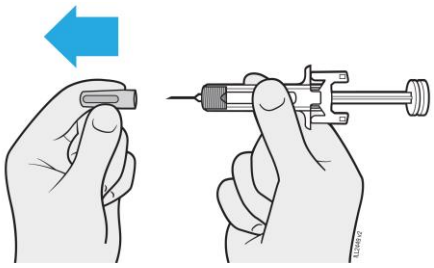
3d Wash hands thoroughly with soap and water.

3e Clean injection site with alcohol wipe.
- Let your skin dry on its own.
- **Do not** touch this area before injecting.

4 Injecting WEZENLA

4a Pull the needle cap straight off while holding the syringe body.

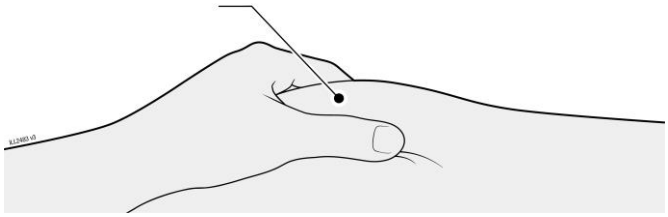
Important: Only remove the cap when you can inject right away (within 5 minutes) because the medicine can dry out.



- **Do not** twist or bend the needle cap.
- **Never** put the cap back on. It may damage the needle.
- **Do not** let anything touch the needle once the cap is removed.
- **Do not** place uncapped pre-filled syringe on any surface once the cap is removed.
- **Do not** try to push air bubbles out. It is okay to see air bubbles.
- A drop of medicine is normal.

4b Pinch the skin around the injection site before injection.

PINCH

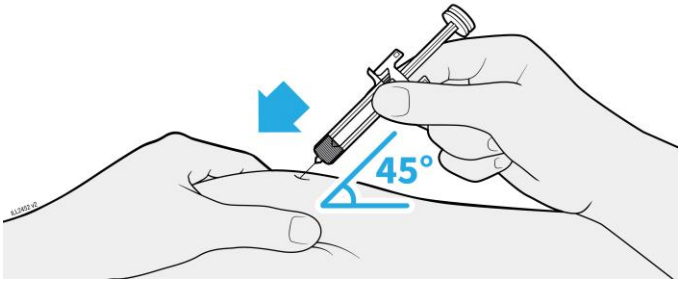


- Pinch the skin between thumb and index finger to create a bump for injection.
- If possible, the bump should be about 5 cm wide.

Important: Continue to pinch the skin until the injection is complete.

4c Insert the needle into the pinched skin.

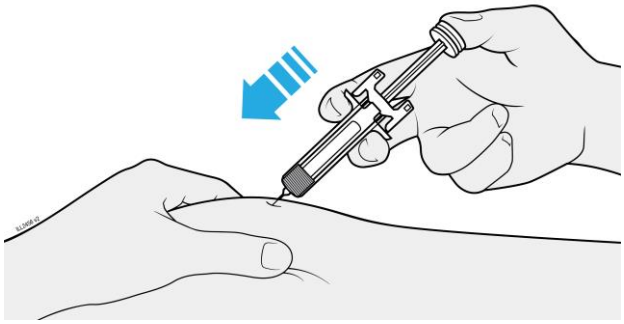
INSERT



- Insert the needle into the pinched skin at a 45-degree angle.
- **Do not** place your finger on the plunger rod while inserting the needle, as this may result in lost medicine.

4d Slowly press the plunger head down until it is completely between the needle guard clips.

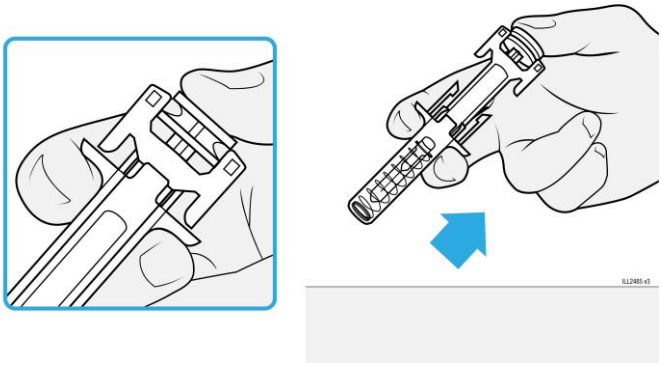
INJECT



- **Do not** pull back on the plunger at any time.
- **Do not** remove pre-filled syringe until all medicine is delivered.

4e Keep pressure on the plunger head and remove needle from skin.

LIFT



- Keep pressure on the plunger head and take the needle out of the skin.
- Let go of the skin after needle is removed.
- Slowly take your thumb off the plunger head. This will let the empty syringe to move up until the entire needle is entirely covered by the needle guard.

If a second injection is required…

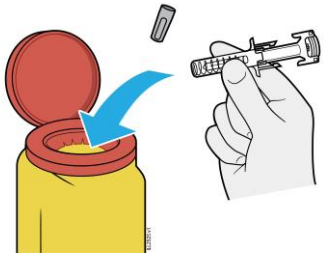
4f Repeat steps 2a-4e if a second injection is required.

- Check your prescription for your dose. If your dose is 90 mg, you will receive either one 90 mg pre-filled syringe or two 45 mg pre-filled syringes.
  - If you receive two 45 mg pre-filled syringes for a 90 mg dose, you will need to give yourself a second injection immediately after the first.
- Repeat Steps 2a–4e for the second injection using a new pre-filled syringe. Choose a different site for the second injection.

5 Disposing and finishing WEZENLA

Important: Never put the cap back on.

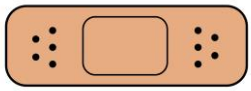
5a Place the used pre-filled syringe and needle cap in the sharps disposal container.

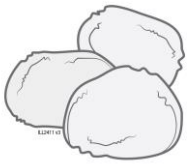


- **Do not** reuse the pre-filled syringe.

Do not throw away the pre-filled syringe into the household waste.

5b Check injection site.





- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply a plaster if necessary.

Any unused product remaining in the syringe should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.