PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Erelzi® 25 mg (solution for injection)

Erelzi® 50 mg (solution for injection)

Etanercept

ERELZI 25 mg contains sugar (5,00 mg sucrose per 0,5 ml pre-filled syringe).

ERELZI 50 mg contains sugar (10,00 mg sucrose per 1,0 ml pre-filled syringe/pen).

Read all this leaflet carefully before you start taking ERELZI.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ERELZI has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ERELZI is and what it is used for.
2. What you need to know before you use ERELZI.
3. How to use ERELZI.
4. Possible side effects.
5. How to store ERELZI.
6. Contents of the pack and other information.
7. Instructions for Use of the ERELZI pre-filled syringe.
8. Instructions for Use of the ERELZI SensoReady pen.

1. What ERELZI is and what it is used for

ERELZI is a medicine that is made from two human proteins. It blocks the activity of another protein in the body that causes inflammation. ERELZI works by reducing the inflammation associated with certain diseases.
In adults (aged 18 and over), ERELZI can be used for moderate or severe rheumatoid arthritis, psoriatic arthritis, severe axial spondyloarthritis including ankylosing spondylitis, and moderate or severe psoriasis.
In each case usually when other widely used treatments have not worked well enough or are not suitable for you.

For rheumatoid arthritis, ERELZI is usually used in combination with methotrexate, although it may also be used alone if treatment with methotrexate is unsuitable for you. Whether used alone or in combination with methotrexate, ERELZI can slow down the damage to your joints caused by the rheumatoid arthritis and improve your ability to do normal daily activities.

For psoriatic arthritis patients with multiple joint involvement, ERELZI can improve your ability to do normal daily activities.

For patients with multiple symmetrical painful or swollen joints (e.g., hands, wrists, and feet), ERELZI can slow down the structural damage to those joints caused by the disease.

ERELZI is also prescribed for the treatment of the following diseases in children and adolescents:

- For the following types of juvenile idiopathic arthritis when treatment with methotrexate has not worked well enough or is not suitable for them:
    - Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in patients from the age of 2 years and weighing 62,5 kg or more.
    - Psoriatic arthritis in patients from the age of 12 years and weighing 62,5 kg or more.
- For enthesitis-related arthritis in patients from the age of 12 years and weighing 62,5 kg or more when other widely used treatments have not worked well enough or are not suitable for them.
- Severe psoriasis in patients from the age of 6 years and weighing 62,5 kg or more who have had an inadequate response to (or are unable to take) phototherapies or other systemic therapies.

2. What you need to know before you use ERELZI

Do not use ERELZI

- if you or the child you are caring for, are **allergic to etanercept** or any of the **other ingredients of ERELZI** (listed in section 6). If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more ERELZI, and contact your doctor immediately.
- if you or the child have or are at risk of developing a **serious blood infection** called sepsis (blood poisoning). If you are not sure, please contact your doctor.
- if you or the child have an **infection of any kind** including tuberculosis or chronic infections and local infections (such as a leg ulcer). If you are not sure, please talk to your doctor.

Warnings and precautions

Tell your doctor or health care provider before taking ERELZI:

- **Allergic reactions**: If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more ERELZI, and contact your doctor immediately.
- **Infections/surgery**: If you or the child develop a new infection, or are about to have any major surgery, your doctor may wish to monitor the treatment with ERELZI.
- **Infections/diabetes**: Tell your doctor if you or the child have a history of recurrent infections or suffer from diabetes or other conditions that increase the risk of infection.
- **Infections/monitoring**: If you or the child develop symptoms of an infection such as fever, chills or cough, notify your doctor immediately. Your doctor may decide to continue to monitor you or the child for the presence of infections after you or the child stop using ERELZI.
- **Tuberculosis**: As cases of tuberculosis have been reported in patients treated with ERELZI, your doctor will check for signs and symptoms of tuberculosis before starting ERELZI. This may include a thorough medical history, a chest X-ray and a tuberculin test. The conduct of these tests should be recorded on the Patient Card. It is very important that you tell your doctor if you or the child have ever had tuberculosis, HIV-infection or have been in close contact with someone who has had tuberculosis. If symptoms of tuberculosis (such as persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.
- **Hepatitis B**: Tell your doctor if you or the child have or have ever had hepatitis B. Your doctor should test for the presence of hepatitis B infection before you or the child begin treatment with ERELZI. Treatment with ERELZI may result in reactivation of hepatitis B in patients who have previously been infected with the hepatitis B virus. If this occurs, you should stop using ERELZI.

- **Hepatitis C**: Tell your doctor if you or the child have hepatitis C. Your doctor may wish to monitor the treatment with ERELZI in case the infection worsens.
- **Blood disorders**: Seek medical advice immediately if you or the child have any signs or symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. Such symptoms may point to the existence of potentially life-threatening blood disorders, which may require discontinuation of ERELZI.
- **Nervous system and eye disorders**: Tell your doctor if you or the child have multiple sclerosis, optic neuritis (inflammation of the nerves of the eyes) or transverse myelitis (inflammation of the spinal cord). Your doctor will determine if ERELZI is an appropriate treatment.
- **Congestive heart failure**: Tell your doctor if you or the child have a history of congestive heart failure, because ERELZI needs to be used with caution under these circumstances.
- **Cancer**: Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given ERELZI. Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher than average risk of developing lymphoma. Children and adults taking ERELZI may have an increased risk of developing lymphoma or another cancer. Some children and teenage patients who have received ERELZI or other medicines that work the same way as ERELZI have developed cancers, including unusual types, which sometimes resulted in death. Some patients receiving ERELZI have developed skin cancers. Tell your doctor if you or the child develop any change in the appearance of the skin or growths on the skin.
- **Chickenpox**: Tell your doctor if you or the child are exposed to chickenpox when using ERELZI. Your doctor will determine if preventive treatment for chickenpox is appropriate.
- **Alcohol abuse**: ERELZI should not be used for the treatment of hepatitis related to alcohol abuse. Please tell your doctor if you or the child in your care have a history of alcohol abuse.
- **Wegener's granulomatosis**: ERELZI is not recommended for the treatment of Wegener's granulomatosis, a rare inflammatory disease. If you or the child in your care have Wegener's granulomatosis, talk to your doctor.
- **Anti-diabetic medicines**: Tell your doctor if you or the child have diabetes or are taking medicines to treat diabetes.

Children and adolescents

ERELZI is not indicated for use in children and adolescents who weigh less than 62,5 kg.

- **Vaccinations**: If possible, children should be up to date with all vaccinations before using ERELZI. Some vaccines, such as oral polio vaccine, should not be given while using ERELZI. Please consult your doctor before you or the child receive any vaccines.
- **Inflammatory bowel disease (IBD)**: There have been cases of IBD in patients with juvenile idiopathic arthritis (JIA) treated with ERELZI. Tell the doctor if the child develops any abdominal cramps and pain, diarrhoea, weight loss or blood in the stool.

ERELZI should not normally be used in children with polyarthritis or extended oligoarthritis below the age of 2 years or weighing less than 62,5 kg, or in children with enthesitis-related arthritis or psoriatic arthritis below the age of 12 years or weighing less than 62,5 kg, or in children with psoriasis below the age of 6 years or weighing less than 62,5 kg.

Other medicines and ERELZI

Always tell your health care provider if you or your child are taking, have recently taken or might take any other medicines (including anakinra, abatacept or sulfasalazine). (This includes all complementary or traditional medicines.)

ERELZI should NOT be used together with:

- Live attenuated vaccines, such as the oral polio vaccine.
- Anakinra as it may increase the risk of serious infection and blood disorders.
- Abatacept as it may increase the incidence of serious adverse events.
- Sulfasalazine as it may decrease your white blood cell count.
- Any other medicine in the same syringe

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please contact your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

You should not be treated with ERELZI if you are pregnant or breastfeeding.

Safety in pregnancy and lactation has not been established.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, eye inflammation may be experienced.

Important information about some of the ingredients of ERELZI

ERELZI contains sucrose, which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ERELZI.

3. How to use ERELZI

Do not share medicines prescribed for you with any other person.

Always use ERELZI exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. To help you remember, it may be helpful to write in a diary which day(s) of the week ERELZI should be used. Your doctor will prescribe the appropriate dose for you or your child according to the condition.

Your doctor will tell you how long your treatment with ERELZI will last. Do not stop treatment early.

Use in adult patients (aged 18 years or over)

The usual adult dose of ERELZI for ***rheumatoid arthritis*** is 25 mg given twice a week (3 to 4 days apart) or 50 mg given once weekly and can be administered as follows:

a) once weekly two ERELZI 25 mg pre-filled syringes administered subcutaneously at approximately the same time or
b) one ERELZI 25 mg pre-filled syringe administered twice weekly, 3 to 4 days apart (i.e. two 25 mg pre-filled syringes per week), or
c) ERELZI 50 mg pre-filled syringe or pre-filled pen administered once weekly as a subcutaneous injection.

If you have ***psoriatic arthritis, ankylosing spondylitis or non-radiographic axial spondyloarthritis***, the recommended dose is 50 mg per week given as one ERELZI 25 mg Pre-filled Syringe given twice weekly, 3 to 4 days apart.

Doses other than 25 mg administered twice weekly have not been studied.

If you have ***plaque psoriasis,*** the recommended starting dose of ERELZI for adult patients is 50 mg per week given as one ERELZI 25 mg Pre-filled Syringe administered twice weekly, 3 – 4 days apart or ERELZI 50 mg Pre-filled Syringe or Pre-filled Pen administered once weekly. After three months your doctor will tell you whether to reduce your dose to 50 mg once per week.

Use in children and adolescents

The recommended dose of ERELZI for children with juvenile rheumatoid arthritis, idiopathic arthritis and psoriasis is based upon the child's body weight. Your child's doctor will tell you the amount of ERELZI your child should take.

If you have the impression that the effect of ERELZI is too strong or too weak, talk to your doctor or pharmacist.

See your doctor at regular visits. It is important that your doctor checks your progress to make sure that this medicine is working properly.

Method and route of administration

ERELZI is administered by an injection under the skin (by subcutaneous injection).

ERELZI can be taken with or without food or drink.

Do not mix the ERELZI solution with any other medicine.

If you use more ERELZI than you should

If you have use more ERELZI than you should (either by injecting too much on a single occasion or by using it too frequently), **talk to a doctor or pharmacist immediately**. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to inject ERELZI

If you forget a dose, you should inject it as soon as you remember, unless the next scheduled dose is the next day; in which case you should skip the missed dose. Then continue to inject the medicine on the usual day(s). If you do not remember until the day that the next injection is due, do not take a double dose (two doses on the same day) to make up for a forgotten dose.

If you stop using ERELZI

Your symptoms may return upon discontinuation.

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

4. Possible side effects

ERELZI can cause side effects.

Not all side effects reported for ERELZI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ERELZI, please consult your doctor, pharmacist or other health care professional for advice.

Allergic reactions

If any of the following happen, do not inject more ERELZI. **Tell your doctor immediately or go to the casualty department at your nearest hospital.**

- Trouble swallowing or breathing
- Swelling of the face, throat, hands, or feet
- Feeling nervous or anxious, throbbing sensations, sudden reddening of the skin and/or a warm feeling
- Severe rash, itching, or hives (elevated patches of red or pale skin that often itch)

Serious allergic reactions are rare. However, any of the above symptoms may indicate an allergic reaction to ERELZI, so you should seek immediate medical attention or hospitalisation.

Serious side effects

If you notice any of the following, you or the child may need urgent medical attention.

- Signs of **serious infections** such as high fever that may be accompanied by cough, shortness of breath, chills, weakness, or a hot, red, tender, sore area on the skin or joints;
- Signs of **blood disorders**, such as bleeding, bruising, or paleness;
- Signs of **nerve disorders**, such as numbness or tingling, changes in vision, eye pain, or onset of weakness in an arm or leg;
- Signs of **heart failure** or **worsening heart failure**, such as fatigue or shortness of breath with activity, swelling in the ankles, a feeling of fullness in the neck or abdomen, night-time shortness of breath or coughing, bluish colour of the nails or the lips;

- Signs of **cancers**: cancers may affect any part of the body including the skin and blood, and possible signs will depend on the type and location of the cancer. These signs may include weight loss, fever, swelling (with or without pain), persistent cough, presence of lumps or growths on the skin;
- Signs of **autoimmune reactions** (where antibodies are made that may harm normal tissues in the body) such as pain, itching, weakness, and abnormal breathing, thinking, sensation, or vision;
- Signs of lupus or lupus-like syndrome, such as weight changes, persistent rash, fever, joint or muscle pain, or fatigue;
- Signs of **inflammation of the blood vessels** such as pain, fever, redness or warmth of the skin, or itching.

These are rare or uncommon side effects but are serious conditions (some of which may rarely be fatal). If these signs occur, tell your doctor immediately, or visit the casualty department at your nearest hospital.

The known side effects of ERELZI include the following in groups of decreasing frequency:

Tell your doctor if you notice any of the following:

Frequent side effects:

Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections); headache; and injection site reactions (including bleeding, bruising, redness, itching, pain, and swelling). Reactions at the injection site (these do not occur as often after the first month of treatment). Some patients have developed a reaction at an injection site that was used before.

Allergic reactions; fever; rash; itching; antibodies directed against normal tissue (autoantibody formation).

Less frequent side effects:

Serious infections (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites); worsening of congestive heart failure; low red blood cell count, low white blood cell count, low neutrophil (a type of white blood cell) count; low blood platelet count; skin cancer (excluding melanoma); localised swelling of the skin (angioedema); hives (elevated patches of red or pale skin that often itch); eye inflammation; psoriasis (new or worsening); inflammation of the blood vessels affecting multiple organs; elevated liver blood tests (in patients also receiving methotrexate treatment, the frequency of elevated liver blood tests is common); abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems).

Serious allergic reactions (including severe localised swelling of the skin and wheezing); lymphoma (a type of blood cancer); leukaemia (cancer affecting the blood and bone marrow); melanoma (a type of skin cancer); combined low platelet, red, and white blood cell count; nervous system disorders (with severe muscle weakness and signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord); tuberculosis; new onset congestive heart failure; seizures; lupus or lupus-like syndrome (symptoms may include persistent rash, fever, joint pain, and tiredness); skin rash, which may lead to severe blistering and peeling of the skin; lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes); inflammation of the liver caused by the body's own immune system (autoimmune hepatitis; in patients also receiving methotrexate treatment, the frequency is uncommon); immune disorder that can affect the lungs, skin and lymph nodes (sarcoidosis); inflammation or scarring of the lungs (in patients also receiving methotrexate treatment, the frequency of inflammation or scarring of the lungs is uncommon).
Failure of the bone marrow to produce crucial blood cells.

Frequency unknown:
Merkel cell carcinoma (a type of skin cancer); Kaposi's sarcoma (a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin); excessive activation of white blood cells associated with inflammation (macrophage activation syndrome); recurrence of hepatitis B (a liver infection); worsening of a condition called dermatomyositis (muscle inflammation and weakness with an accompanying skin rash).

Side effects in children and adolescents

The side effects and their frequencies seen in children and adolescents are similar to those described above.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ERELZI.

Suspected adverse reactions can also be reported directly to the HCR via https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store ERELZI

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use this medicine after the expiry date which is stated on the carton and the label of the pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C). Do not freeze.

Keep the pre-filled syringes/pens in the outer carton in order to protect from light.

After taking a syringe/pen from the refrigerator, **wait approximately 15-30 minutes to allow the ERELZI solution in the syringe to reach room temperature.** Do not warm in any other way. Immediate use is then recommended.

The needle cap should not be removed while allowing the pre-filled syringe to reach room temperature.

ERELZI may be stored outside of the refrigerator at temperatures up to a maximum of 25 °C for a single period of up to four weeks; after which, it should not be refrigerated again. ERELZI should be discarded if not used within four weeks after removal from the refrigerator. It is recommended that you record the date that ERELZI is removed from the refrigerator and the date after which ERELZI should be discarded (no more than 4 weeks following the removal from the refrigerator).

Inspect the solution in the syringe/pen. It should be clear or slightly opalescent, colourless to slightly yellowish, and may contain small white or almost translucent particles of protein. This appearance is normal for ERELZI.

Do not use the solution if it is discoloured, cloudy, or if particles other than those described above are present.

If you are concerned with the appearance of the solution, then contact your pharmacist for assistance.

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 ERELZI contains

The active substance is etanercept.

Each pre-filled syringe contains 25 mg of etanercept or 50 mg of etanercept.

The other ingredients are citric acid anhydrous, L-lysine hydrochloride, sodium chloride, sodium citrate dihydrate, sucrose, water for injections.

What ERELZI looks like and contents of the pack

ERELZI is supplied as a pre-filled syringe or pre-filled pen containing a colourless to slightly yellowish solution for injection, practically free from extraneous particles.

25 mg: Each pack contains 1, 2 or 4 pre-filled syringes with a needle guard, multipacks contain 12 (3 packs of 4) or 8 (2 packs of 4) or 24 (6 packs of 4) 25 mg pre-filled syringes with a needle guard.

50 mg: Each pack contains 1, 2 or 4 pre-filled syringes or pre-filled pens with a needle guard, multipacks contain 12 (3 packs of 4) pre-filled syringes or pre-filled pens with a needle guard.

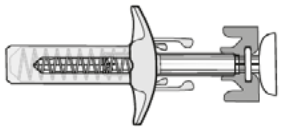
Not all pack sizes may be marketed.

7. Instructions for Use of the ERELZI pre-filled syringe

Read ALL the way through these instructions before injecting.

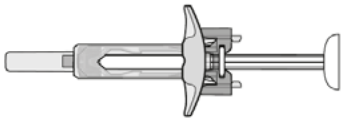
It is important not to try to inject yourself until you have been trained by your doctor, nurse, pharmacist or health care provider. The box contains ERELZI pre-filled syringe(s) individually sealed in a plastic blister.

DO NOT USE

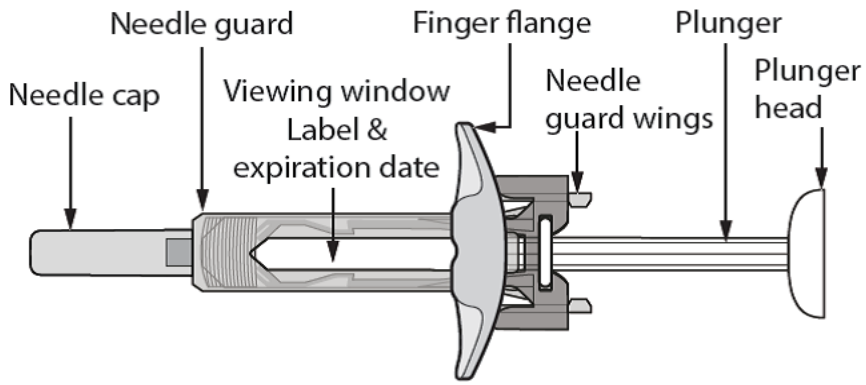


In this configuration the needle guard is ACTIVATED – DO NOT USE the pre-filled syringe

READY TO BE USED



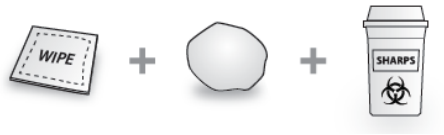
In this configuration the needle guard is NOT ACTIVATED and the pre-filled syringe is ready for use



After the medicine has been injected, the needle guard will be activated to cover the needle. This is intended to aid in the protection of healthcare professionals, patients who self-inject doctor-prescribed medicines and individuals who assist self-injecting patients from accidental needle stick injuries.

What you additionally need for your injection:

- Alcohol wipe
- Cotton ball or gauze
- Sharps disposal container

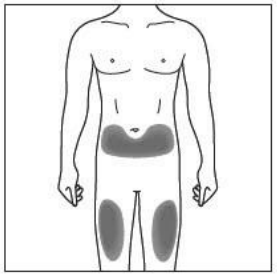


Important safety information

Caution: Keep the syringe out of the sight and reach of children.

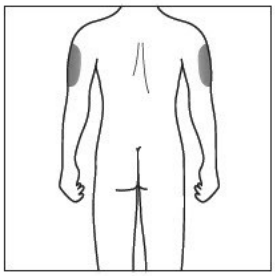
1. Do not open the outer box until you are ready to use this medicine.
2. Do not use this medicine if the seal of the blister is broken, as it may not be safe for you to use.
3. Do not shake the syringe.
4. Never leave the syringe lying around where others might tamper with it.
5. The pre-filled syringe has a needle guard that will be activated to cover the needle after the injection is finished. The needle guard will help to prevent needle stick injuries to anyone who handles the pre-filled syringe. Be careful not to touch the needle guard wings before use. By touching them, the needle guard may be activated too early.
6. Do not remove the needle cap until just before you give the injection.
7. The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.

The injection site



The injection site is the place on the body where you are going to use the pre-filled syringe.

- The recommended site is the front of your thighs. You may also use the lower abdomen, but not the area 5 centimeters around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should NOT inject directly into any raised, thick, red, or scaly skin patches or lesions (“psoriasis skin lesions”).



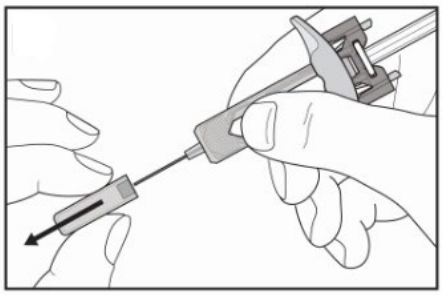
If a caregiver is giving you the injection, the outer upper arms may also be used.

Preparing the ERELZI pre-filled syringe

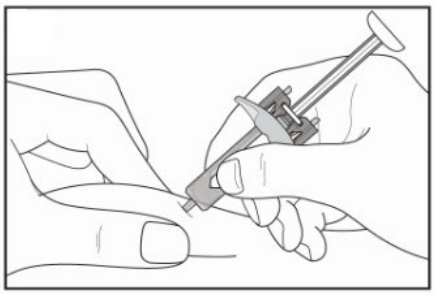
1. Take the blister out of the refrigerator and leave it unopened for about 15–30 minutes so that it reaches room temperature.
2. When you are ready to use the syringe, open the blister and wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Take the syringe out of the blister.
5. Inspect the syringe. The liquid should be clear or slightly opalescent, colourless to slightly yellowish, and may contain small white or almost translucent particles of protein. This appearance is normal for ERELZI.

Do not use if the liquid is cloudy, discoloured, or has large lumps, flakes, or coloured particles. Do not use if the syringe is broken or the needle guard is activated. In all these cases, return the entire product pack to the pharmacy.

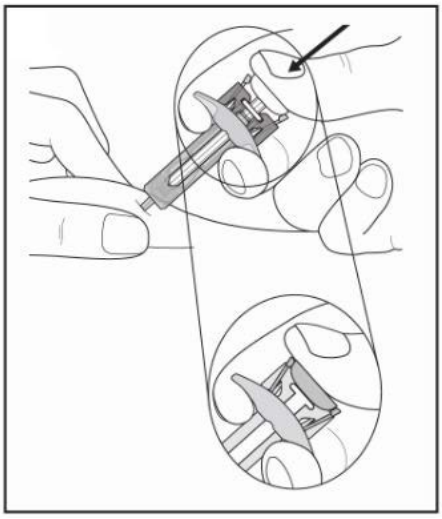
How to use the ERELZI pre-filled syringe



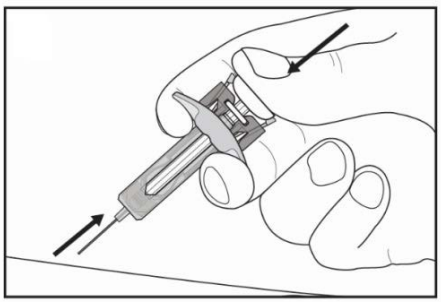
Carefully remove the needle cap from the syringe. Discard the needle cap.
You may see a drop of liquid at the end of the needle. This is normal.



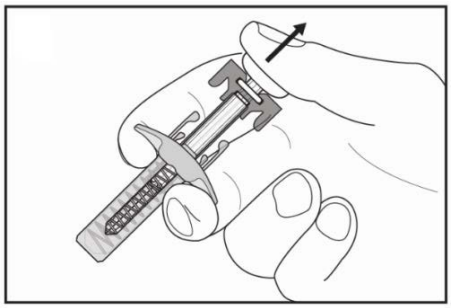
Gently pinch the skin at the injection site and insert the needle as shown.
Push the needle all the way in to ensure that the medicine can be fully administered.



Hold the syringe finger flange as shown. Slowly press the plunger as far as it will go, so that the plunger head is completely between the needle guard wings.
Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.

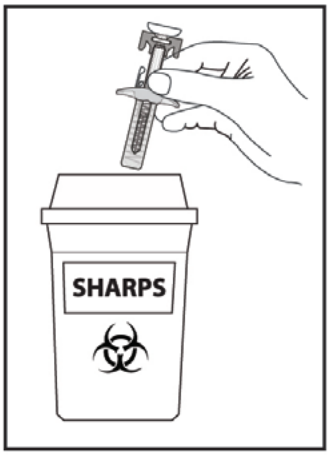


Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.



Slowly release the plunger and allow the needle guard to automatically cover the exposed needle.
There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

Disposal instructions



Dispose of the used syringe in a sharps container (closable, puncture-resistant container). For the safety and health of you and others, needles and used syringes must never be re-used.

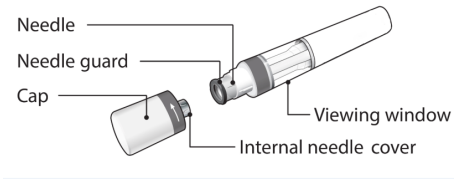
If you have any questions, please talk to a doctor, nurse, pharmacist or healthcare provider who is familiar with ERELZI.

8. Instructions for Use of the ERELZI SensoReady pen

Read ALL the way through these instructions before injecting.

These instructions are to help you to inject correctly using the ERELZI SensoReady pen.
It is important not to try to inject yourself until you have been trained by your doctor, nurse, pharmacist or healthcare provider.

Your ERELZI SensoReady pen:



ERELZI SensoReady pen shown with the cap removed. Do not remove the cap until you are ready to inject.

Store your boxed pen in a refrigerator, between 2 °C to 8 °C and out of the sight and reach of children.

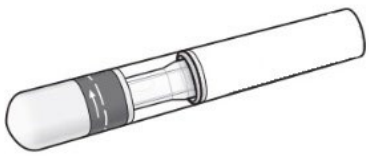
- Do not freeze the pen.
- **Do not shake** the pen.
- Do not use the pen if it has been dropped with the cap removed.

For a more comfortable injection, take the pen out of the refrigerator 15-30 minutes before injecting to allow it to reach room temperature.

What you need for your injection:

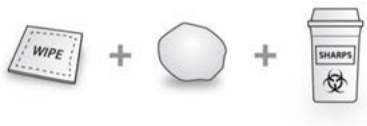
Included in the carton:

A new and unused ERELZI SensoReady pen.

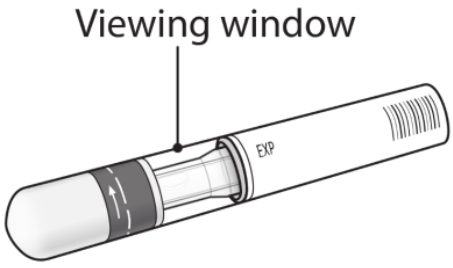


Not included in the carton:

- Alcohol wipe
- Cotton ball or gauze
- Sharps disposal container



Before your injection:



1. Important safety checks before you inject:

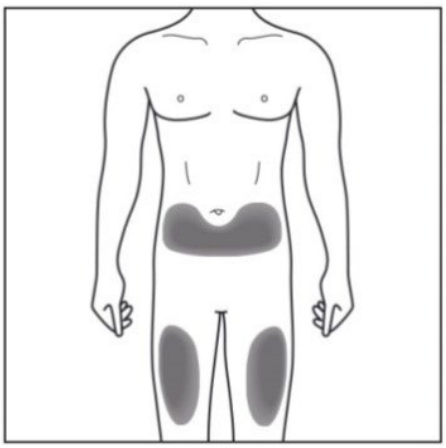
The solution should be clear or slightly opalescent, colourless to slightly yellowish, and may contain small white or almost translucent particles of protein. This appearance is normal for ERELZI.

Do not use if the liquid is cloudy, discoloured, or has large lumps, flakes, or coloured particles.

Do not use the pen if the expiry date has passed.

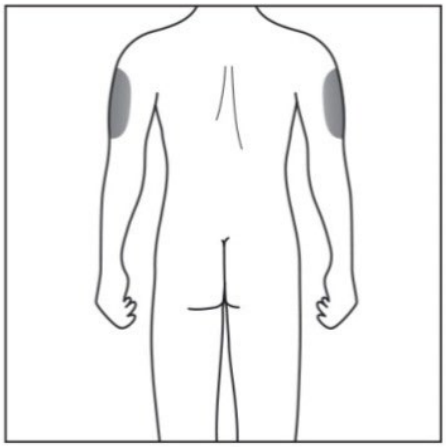
Do not use if the safety seal has been broken.

Contact your pharmacist if the pen fails any of these checks.



2a. Choose your injection site:

- The recommended site is the front of the thighs. You may also use the lower abdomen, but not the area 5 centimetres around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should NOT inject directly into any raised, thick, red, or scaly skin patches or lesions (“psoriasis skin lesions”).



2b. Caregivers and healthcare professionals only:

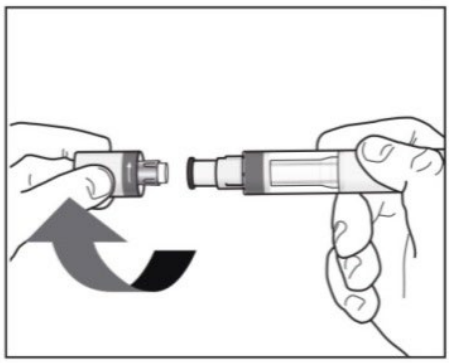
- If a caregiver or healthcare professional is giving you your injection, they may also inject into your outer upper arm.



3. Cleaning your injection site:

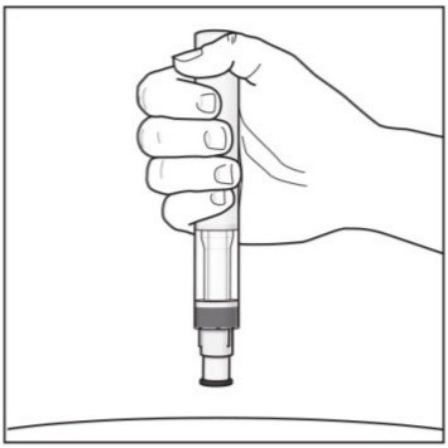
- Wash your hands with soap and hot water.
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.
- Do not touch the cleaned area again before injecting.

Your injection:



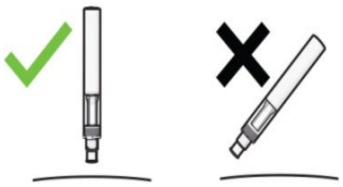
4. Removing the cap:

- Only remove the cap when you are ready to use the pen.
- Twist off the cap in the direction of the arrows.
- Once removed, throw away the cap. Do not try to re-attach the cap.
- Use the pen within 5 minutes of removing the cap.



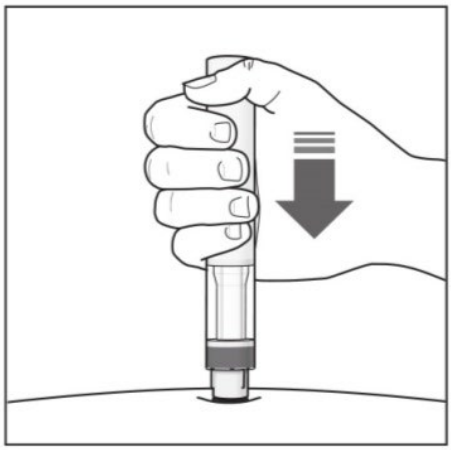
5. Holding your pen:

- Hold the pen at 90 degrees to the cleaned injection site.



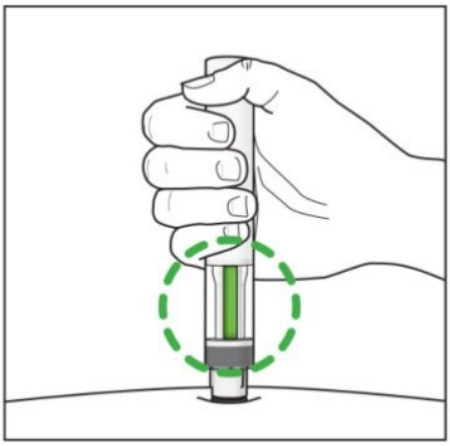
Correct **Incorrect**

	**YOU MUST READ THIS BEFORE INJECTING.** During the injection you will hear 2 loud clicks. The 1st click indicates that the injection has started. Several seconds later a 2nd click will indicate that the injection is almost finished. You must keep holding the pen firmly against your skin until you see a green indicator fill the window and stop moving.



6. Starting your injection:

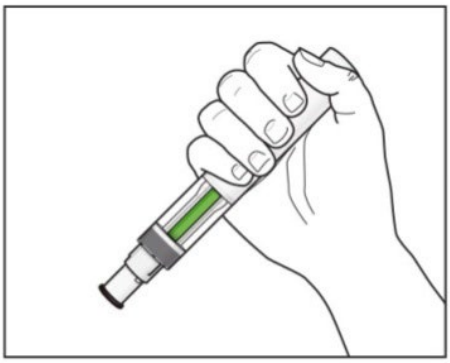
- Press the pen firmly against the skin to start the injection.
- The 1st click indicates the injection has started.
- Keep holding the pen firmly against your skin.
- The green indicator shows the progress of the injection.



7. Completing your injection:

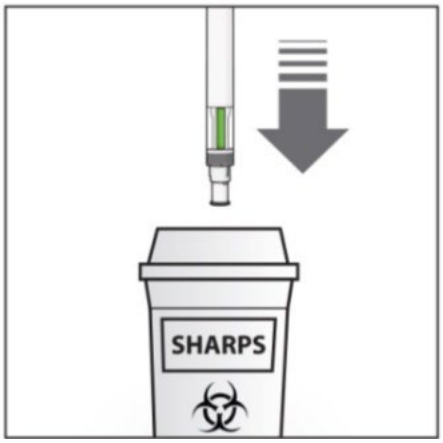
- Listen for the 2nd click. This indicates the injection is almost complete.
- Check the green indicator fills the window and has stopped moving.
- The pen can now be removed.

After your injection:



8. Check the green indicator fills the window:

- This means the medicine has been delivered. Contact your doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.



9. Disposing of your ERELZI pen:

- Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).
- Never try to re-use your pen.

If you have any questions, please talk to a doctor, nurse or pharmacist who is familiar with ERELZI.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Waterfall 5-Ir

Magwa Crescent West

Waterfall City

Jukskei View

2090

This leaflet was last revised in

26 January 2022

Registration numbers

ERELZI 25 mg: 55/3.1/0392

ERELZI 50 mg: 55/3.1/0393

[1]Company Reg. No.: 1990/001979/07