

PACKAGE LEAFLET: INFORMATION FOR THE USER

Simponi 50 mg solution for injection in a pre-filled pen golimumab

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Your doctor will also give you a Patient Alert Card, which contains important safety information you need to be aware of before and during your treatment with Simponi.

In this leaflet:

1. What Simponi is and what it is used for
2. Before you use Simponi
3. How to use Simponi
4. Possible side effects
5. How to store Simponi
6. Further information

1. WHAT SIMPONI IS AND WHAT IT IS USED FOR

Simponi contains the active substance called golimumab.

Simponi belongs to a group of medicines called ‘TNF blockers’. It is used in adults for the treatment of the following inflammatory diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis

Simponi works by blocking the action of a protein called ‘tumour necrosis factor alpha’ (TNF- α). This protein is involved in inflammatory processes of the body, and blocking it can reduce the inflammation in your body.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. If you have active rheumatoid arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given Simponi which you will take in combination with another medicine called methotrexate to:

- Reduce the signs and symptoms of your disease.
- Improve your physical function.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis, an inflammatory disease of the skin. 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 Simponi to:

- Reduce the signs and symptoms of your disease.
- Improve your physical function.

Ankylosing spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine. If you have ankylosing spondylitis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given Simponi to:

- Reduce the signs and symptoms of your disease.
- Improve your physical function.

2. BEFORE YOU USE SIMPONI

Do not use Simponi

- If you are allergic (hypersensitive) to golimumab or any of the other ingredients of Simponi (listed in Section 6 “What Simponi contains”).
- If you have tuberculosis (TB) or any other severe infection.
- If you have moderate or severe heart failure.

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

Take special care with Simponi

Tell your doctor before using Simponi if you have any of the following:

Infections

Tell your doctor straight away if you already have or get any symptoms of infection, during or after your treatment with Simponi. Symptoms of infection include fever, cough, shortness of breath, flu-like symptoms, diarrhoea, wounds, dental problems or a burning feeling when urinating.

- You may get infections more easily while using Simponi.
- Infections may progress more rapidly and may be more severe. In addition, some previous infections may reappear.

Tuberculosis (TB)

Tell your doctor straight away if symptoms of TB appear during or after your treatment.

Symptoms of TB include persistent cough, weight loss, tiredness, fever or night sweats.

- Cases of TB have been reported in patients treated with Simponi. Your doctor will test you to see if you have TB. Your doctor will record these tests on your Patient Alert Card.
- It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had or has TB.
- If your doctor feels that you are at risk of TB, you may be treated with medicines for TB before you begin using Simponi.

Hepatitis B virus (HBV)

Tell your doctor if you are a carrier or if you have HBV or if you think you might be at risk of contracting HBV.

- Treatment with TNF blockers such as Simponi may result in reactivation of HBV in patients who carry this virus, which can be life-threatening in some cases.

Invasive fungal infections

If you have lived in or travelled to an area where infections caused by specific type of fungi that can affect the lungs or other parts of the body (called histoplasmosis, coccidioidomycosis, or blastomycosis), are common, tell your doctor straight away. Ask your doctor if you don't know if these fungal infections are common in the area in which you have lived or travelled

Vaccinations

Talk to your doctor if you have had, or are due to have a vaccine.

- You should not receive certain (live) vaccines while using Simponi.

Operations or dental procedures

- Talk to your doctor if you are going to have any operations or dental procedures.
- Tell your surgeon or dentist performing the procedure that you are having treatment with Simponi by showing them your Patient Alert Card.

Cancer and lymphoma

Tell your doctor if you have ever been diagnosed with lymphoma (a type of blood cancer) or any other cancer before you use Simponi.

- If you use Simponi or other TNF blockers, your risk for developing lymphoma or another cancer may increase.
- Patients with severe rheumatoid arthritis and other inflammatory diseases, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
- Patients with severe persistent asthma, chronic obstructive pulmonary disease (COPD), or are heavy smokers may be at increased risk for cancer with Simponi treatment. If you have severe persistent asthma, COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

Heart failure

Tell your doctor straight away if you get new or worsening symptoms of heart failure. Symptoms of heart failure include shortness of breath or swelling of your feet.

- New and worsening congestive heart failure has been reported with TNF blockers.
- If you have mild heart failure and you are being treated with Simponi, you must be closely monitored by your doctor.

Nervous system disease

Tell your doctor straight away if you have ever been diagnosed with or develop symptoms of a demyelinating disease such as multiple sclerosis. Symptoms may include changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body. Your doctor will decide if you should receive Simponi.

Autoimmune disease

Tell your doctor if you develop symptoms of a disease called lupus. Symptoms include persistent rash, fever, joint pain and tiredness.

- On rare occasions, people treated with TNF blockers have developed lupus.

Blood disease

In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.

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

Using other medicines

- You should not take Simponi with medicines containing the active substance anakinra or abatacept. These medicines are used for the treatment of rheumatic diseases.
- Tell your doctor or pharmacist if you are taking any other medicines that affect your immune system.
- You should not receive certain (live) vaccines while using Simponi.
- Tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

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

Pregnancy and breast-feeding

Talk to your doctor before using Simponi if:

- You are pregnant or are planning to become pregnant while using Simponi. The effects of this medicine in pregnant women are not known. The use of Simponi in pregnant women is not recommended. If you are being treated with Simponi, you must avoid becoming pregnant by using adequate contraception during your treatment and for at least 6 months after the last Simponi injection.
- You are a (potential) nursing mother. Before starting breast-feeding, your last treatment with Simponi must be at least 6 months ago. You must stop breast-feeding if you are to be given Simponi.

Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

Simponi may have a minor influence on your ability to drive and use tools or machines. Dizziness may occur after you take Simponi. If this happens, do not drive or use any tools or machines.

Important information about some of the ingredients of Simponi

Latex sensitivity

A part of the pre-filled pen, the needle cover, contains latex. Because latex may cause severe allergic reactions, talk to your doctor before using Simponi if you or your carer are allergic to latex.

Sorbitol intolerance

Simponi contains sorbitol (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO USE SIMPONI

Always use Simponi exactly as your doctor has told you. You should check with your doctor if you are not sure.

Simponi is not recommended for children and adolescents (younger than 18 years) because it has not been studied in this age group.

How much Simponi is given

- The recommended dose is 50 mg (the content of 1 pre-filled pen) given once a month, on the same date each month.
- Talk to your doctor before taking your fourth dose. Your doctor will determine if you should continue Simponi treatment.
 - If you weigh more than 100 kg, the dose might be increased to 100 mg (the content of 2 pre-filled pens) given once a month, on the same date each month.

How Simponi is given

- Simponi is given by injection under the skin (subcutaneously).
- At the start, your doctor or nurse may inject Simponi. However, you and your doctor may decide that you may inject Simponi yourself. In this case you will get training on how to inject Simponi yourself.

Talk to your doctor if you have any questions about giving yourself an injection. You will find detailed “Instructions for administration” at the end of this leaflet.

If you use more Simponi than you should

If you have used or been given too much Simponi (either by injecting too much on a single occasion, or by using it too often), talk to your doctor or pharmacist straight away. Always take the outer carton with you, even if it is empty.

If you forget to use Simponi

If you forget to use Simponi on your planned date, inject the forgotten dose as soon as you remember.

Do not use a double dose to make up for a forgotten dose.

When to inject your next dose:

- If you were less than 2 weeks late, inject the forgotten dose as soon as you remember and stay on your original schedule.
- If you were more than 2 weeks late, inject the forgotten dose as soon as you remember and talk to your doctor or pharmacist to ask when you need to take the next dose.

If you are not sure what to do, talk your doctor or pharmacist.

If you stop using Simponi

If you are considering stopping Simponi, talk to your doctor or pharmacist first.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simponi can cause side effects, although not everybody gets them. Some patients may experience serious side effects and may require treatment. Side effects may appear up to several months after the last injection.

Tell your doctor straight away if you notice any of the following:

- **Symptoms of an allergic reaction** such as swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles.
- **Symptoms of an infection (including TB)** such as fever, tiredness, (persistent) cough, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems and a burning feeling when urinating.
- **Symptoms of liver problems** such as yellowing of the skin and eyes, dark brown-coloured urine, right-sided abdominal pain, fever, feeling sick, being sick, and feeling very tired .

Side effects may occur with certain frequencies, which are defined as follows:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

Not known (frequency cannot be estimated from the available data)

The following side effects have been observed with Simponi:

Very common side effects:

- Upper respiratory tract infections, sore throat or hoarseness, runny nose

Common side effects:

- Abnormal liver tests (increased liver enzymes) found during blood tests done by your doctor
- Feeling dizzy
- Headache
- Superficial fungal infections
- Bacterial infections (such as cellulitis)
- Low red blood cell counts
- Positive blood lupus test
- Difficulty sleeping
- Depression

- Constipation
- Hair loss
- Allergic reactions
- Rash and itching of the skin
- Indigestion
- Stomach pain
- Feeling numb or having a tingling feeling
- Flu
- Bronchitis
- Sinus infection
- Cold sores
- High blood pressure
- Fever
- Injection site reactions (including redness, hardness, pain, bruising, itching, tingling and irritation)
- Feeling weak
- Impaired healing
- Chest discomfort

Uncommon side effects:

- Serious blood infections
- TB
- lower respiratory tract infection (including pneumonia)
- Infection of the joints or the tissue around them
- Kidney infection
- Abscess
- Infections which may occur in people with weakened immune system, such as fungal infections affecting lungs or other body parts
- cancers, including skin cancer and non-cancerous growths or lumps, including skin moles
- Psoriasis (also in the form of skin blisters)
- Nervous system disease (symptoms may include changes in vision, weak arms or legs)
- Low platelet count
- Low white blood cell counts
- Combined low platelet, red, and white blood cell count
- Thyroid disorders
- Increase in blood sugar levels
- Increase in blood cholesterol levels
- Balance disorders
- Taste disturbances
- Vision disturbances
- New onset or worsening congestive heart failure
- Sensation of heart beating irregularly
- Narrowing of the blood vessels in the heart
- Blood clots
- Pain and discoloration in the fingers or toes
- Flushing
- Asthma, shortness of breath, wheezing
- Stomach and bowel disorders which include inflammation of the stomach lining and colon which may cause fever
- Acid reflux
- Pain and ulcers in the mouth
- Gall stones
- Liver disorders

- Bladder disorders
- Breast disorders
- Menstrual disorders
- Bone fractures

Rare side effects:

- Cancer of the lymph system
- Hepatitis B reactivation
- Chronic inflammatory condition of the lungs
- Lupus-like syndrome
- Kidney disorders

Side effects of which the frequency is not known:

- Failure of the bone marrow to produce blood cells

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE SIMPONI

Keep out of the reach and sight of children.

Do not use Simponi 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.

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

Keep the pre-filled pen in the outer carton in order to protect it from light.

Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Simponi contains

The active substance is golimumab. One 0.5 ml pre-filled pen contains 50 mg of golimumab.

The other ingredients are sorbitol (E420), L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 and water for injections.

What Simponi looks like and contents of the pack

Simponi is supplied as solution for injection in a single-use pre-filled pen. Simponi is available in packs containing 1 pre-filled pen and multipacks containing 3 (3 packs of 1) pre-filled pens. Not all pack sizes may be marketed.

The solution is clear to slightly opalescent (having a pearl-like shine), colourless to light yellow and may contain a few small translucent or white particles of protein. Do not use Simponi if the solution is discoloured, cloudy or you can see foreign particles in it.

Marketing Authorisation Holder and Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last approved in 10/2009.

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>.

INSTRUCTIONS FOR ADMINISTRATION

If you would like to self inject Simponi , you must be trained by a healthcare professional to prepare an injection and give it to yourself. If you have not been trained, please contact your doctor, nurse or pharmacist to schedule a training session.

The diagram below (see figure 1) shows what the "SmartJect" pre-filled pen looks like. In this leaflet "SmartJect" pre-filled pen may sometimes be shortened to "pen".

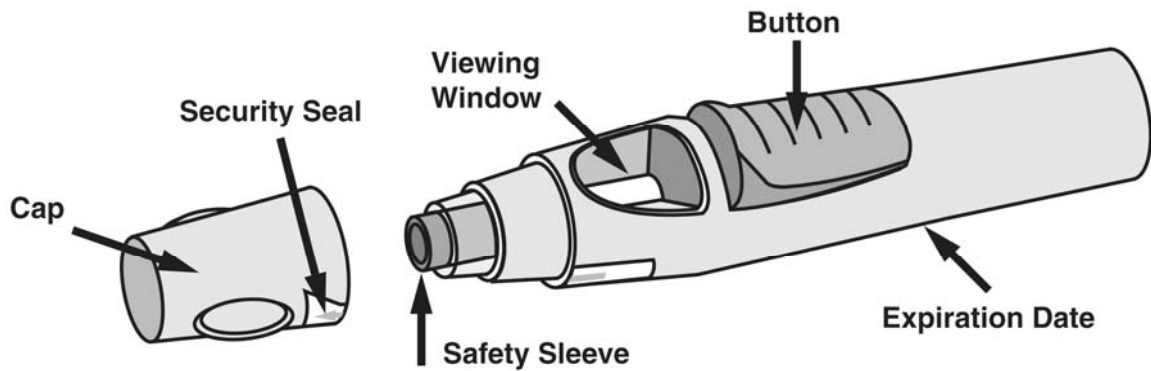


Figure 1

Preparing for use of the pen

- Do not shake the pen at any time.
- Do not remove the cap from the pen until instructed to do so.

1. Check expiry date

- Check the expiration date (as indicated as “EXP”) on the pen.
- You can also check the expiration date printed on the carton.

Do not use the pen if the expiration date has passed. Please contact your doctor or pharmacist for assistance.

2. Check security seal

- Check the security seal around the cap of the pen.

Do not use the pen if the seal is broken. Please contact your doctor or pharmacist.

3. Wait 30 minutes

- To ensure proper injection, allow the pen to sit at room temperature outside the box for 30 minutes out of the reach of children.

Do not warm the pen in any other way (for example, do not warm it in a microwave or in hot water). Do not remove the pen’s cap while allowing it to reach room temperature.

4. Get the rest of your equipment ready

While you are waiting you can get the rest of your equipment ready, including an alcohol swab, a cotton ball or gauze and a sharps container.

5. Check the liquid in the pen

- Look through the viewing window to make sure that the liquid in the pen is clear to slightly opalescent (having a pearl-like shine) and colourless to light yellow. The solution may contain a few small translucent or white particles of protein.
- You will also notice an air bubble, which is normal.

Do not use the pen if the liquid is the wrong colour, cloudy, or contains foreign particles. If this happens, talk to your doctor or pharmacist.

Choosing and preparing the injection site

1. Choose your injection site (see figure 2)

- You usually inject the medicine into the front of the middle thighs.
- You can also use the stomach (abdomen) below the belly button, except for the 5 cm area directly underneath the belly button.
- You can use both sites, regardless of your body type or size.

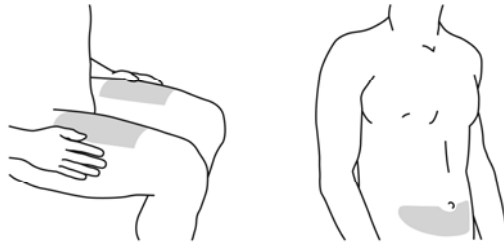


Figure 2

Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars or stretch marks.

2. Injection site selection for caregivers (see figure 3)

- If a caregiver is giving you the injection, they can also use the outer area of the upper arms
- Again, all sites mentioned can be used regardless of your body type or size.

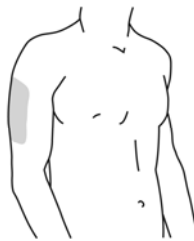


Figure 3

3. Preparing injection site

- Wash your hands thoroughly with soap and warm water.
- Wipe the injection site with an alcohol swab.
- Allow the skin to dry before injecting. Do not fan or blow on the clean area.

Do not touch this area again before giving the injection.

Injecting the medicine

The cap should not be removed until you are ready to inject the medication. The medication should be injected within 5 minutes after the cap has been removed.

1. Remove the cap (figure 4)

- When you are ready to inject, twist the cap slightly to break the security seal.
- Pull the cap off and throw it away.

Do not put the cap back on because it may damage the needle inside the pen. Do not use the pen if it is dropped without the cap in place. If this happens please contact your doctor or pharmacist.

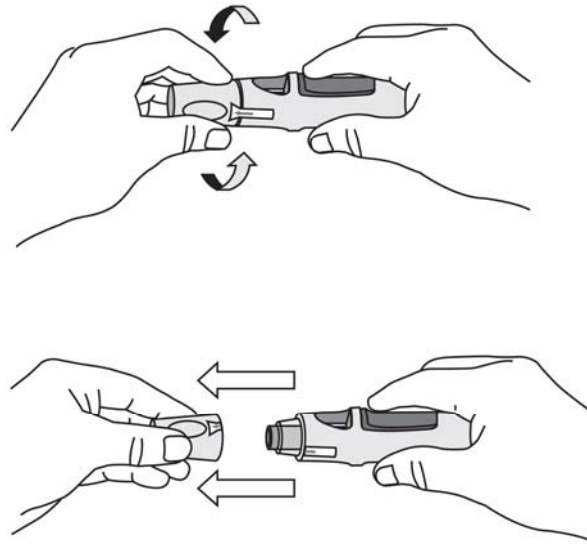


Figure 4

2. Push the pen against the skin (see figure 5)

- Hold the pen comfortably in your hand.
- Without pressing the button, hold the open end of the pen at a right angle (90-degree) against your skin and push the pen down firmly.

Some people find that using their free hand to pinch and hold the skin at the injection site during administration makes injecting easier.

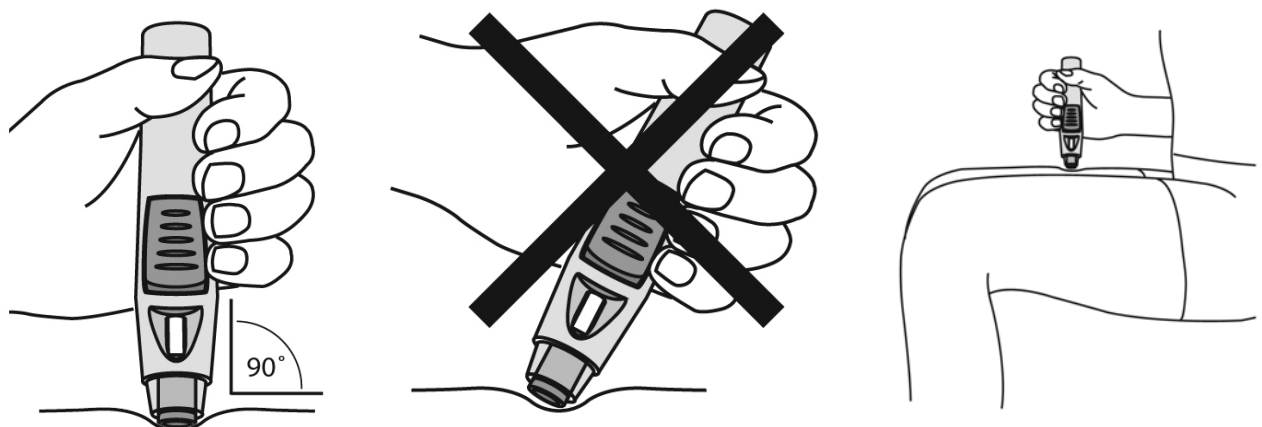


Figure 5

3. Press button to inject (see figure 6)

- Continue to hold the pen firmly against your skin and press the button. Once the button is pressed, it will remain pressed in so you do not need to keep pressure on it.

- The first “click” means the injection has started.

Do not lift the pen yet.

You will not be able to push in the button unless the pen is pushed firmly against the skin.

4. Continue to hold until the second “click” (see figure 6)

- Continue to hold the pen down firmly against your skin until you hear a second “click”. This usually takes about 3-6 seconds, but may take up to 15 seconds.
- The second “click” means that the injection is finished and the needle has gone back into the pen.
- Lift the pen from the injection site.

If you have hearing problem, count 15 seconds from the time you first press the button and then lift the pen from the injection site.

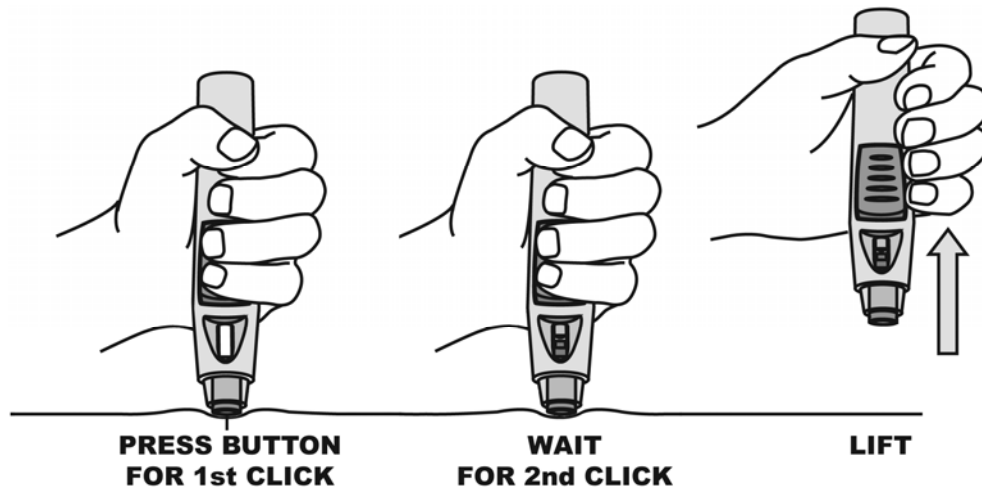


Figure 6

After the injection

1. Use cotton ball or gauze

- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site for 10 seconds.
- You may cover the injection site with a small adhesive bandage, if necessary.

Do not rub your skin.

2. Check the window (see figure 7)

- After injecting, check the viewing window to make sure that a yellow indicator is visible.
- This shows that the pen has worked properly.

Talk to your doctor or pharmacist if the yellow indicator is not visible in the window.

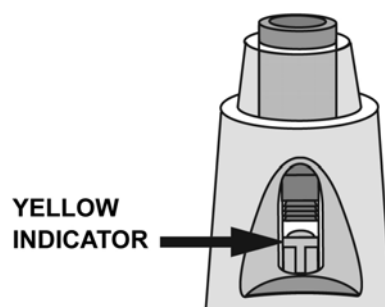


Figure 7

3. Throw the pen away (see figure 8)

- Place your pen in a sharps container straight away. Make sure you dispose of the bin as instructed by your doctor or nurse.

If you feel that something has gone wrong with the injection or if you are not sure, talk to your doctor or pharmacist.



Figure 8