**Package leaflet: Information for the user**

**Benlysta 200 mg solution for injection in pre-filled pen**
belimumab

▼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.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Benlysta is and what it is used for
2. What you need to know before you use Benlysta
3. How Benlysta is used
4. Possible side effects
5. How to store Benlysta
6. Contents of the pack and other information
   Step-by-step instructions for using the pre-filled pen


## 1. What Benlysta is and what it is used for

**Benlysta as a subcutaneous injection is a medicine used to treat lupus** (systemic lupus erythematosus, SLE) in adults (18 years of age and older) and children (5 to under 18 years of age and weighing at least 15 kg) whose disease is still highly active despite standard treatment. Benlysta is also used in combination with other medicines to treat adults (18 years of age and older) with active lupus nephritis (lupus-related kidney inflammation).

Lupus is a disease in which the immune system (the system that fights infection) attacks your own cells and tissues, causing inflammation and organ damage. It can affect almost any organ in the body, and is thought to involve a type of white blood cells called *B cells*.

Benlysta contains **belimumab** (*a monoclonal antibody*). It reduces the number of B cells in your blood by blocking the action of BLyS, a protein that helps B cells to live longer and is found in high levels in people with lupus.

You will be given Benlysta as well as your usual treatment for lupus.

## 2. What you need to know before you use Benlysta

**Do not use Benlysta**

- if you are **allergic** to belimumab or any of the other ingredients of this medicine (listed in section 6).

  ➔ **Check with your doctor** if this may apply to you.

**Warnings and precautions**
Talk to your doctor before you use Benlysta:

- if you have a current or long-term **infection** or if you often get infections. Your doctor will decide if you can be given Benlysta
- if you are planning to have a **vaccination** or have had a vaccination within the last 30 days. Some vaccines should not be given just before or during treatment with Benlysta
- if your lupus affects your **nervous system**
- if you are **HIV positive** or have **low immunoglobulin** levels
- if you have, or have had, **hepatitis B or C**
- if you have had an **organ transplant,** or a **bone marrow** or **stem cell transplant**
- if you have had **cancer**
- if you have ever developed a **severe skin rash** or **skin peeling**, **blistering** and/or **mouth sores** after using Benlysta.

➔ **Tell your doctor** if any of these may apply to you.

**Depression and suicide**
There have been reports of depression, suicidal thoughts, and suicide attempts including suicide during treatment with Benlysta. Tell your doctor if you have a history of these conditions. If you experience new or worsening symptoms at any time:

➔ **Contact your doctor or go to a hospital straight away**.

If you feel depressed or have thoughts of harming yourself or committing suicide, you may find it helpful to tell a relative or close friend and ask them to read this leaflet. You might ask them to tell you if they are worried about changes in your mood or behaviour.

**Severe skin reactions**
Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with Benlysta treatment.

➔ **Stop using Benlysta and seek medical attention immediately if you notice any of the symptoms described in section 4.**

**Look out for important symptoms**
People taking medicines that affect their immune system may be more at risk of infections, including a rare but serious brain infection called *progressive multifocal leukoencephalopathy* (PML).

➔ **Read the information 'Increased risk of brain infection' in section 4 of this leaflet.**

To improve the traceability of this medicine, you and your healthcare provider should record the Benlysta lot number. It is recommended that you make a note of this information in case you are asked for it in the future.

**Children and adolescents**
Benlysta pre-filled pen as a subcutaneous injection is not intended to be used in children younger than 5 years of age or less than 15 kg for the treatment of SLE.

Benlysta pre-filled pen as a subcutaneous injection is not intended to be used in children or adolescents younger than 18 years of age for the treatment of lupus nephritis.

**Other medicines and Benlysta**

**Tell your doctor** if you are taking any other medicines, if you have recently taken or might take any other medicines.

In particular tell your doctor if you are being treated with medicines that affect your immune system, including any medicine that affects your B cells (to treat cancer or inflammatory diseases).

Using such medicines in combination with Benlysta may make your immune system less effective. This could increase your risk of a serious infection.

**Pregnancy and breast-feeding**

**Contraception for women who could become pregnant**

- **Use an effective method of contraception** while you are being treated with Benlysta and for at least 4 months after the last dose.

**Pregnancy**

**Benlysta is not usually recommended if you are pregnant.**

- **Tell your doctor if you are pregnant,** think you may be pregnant, or are planning to have a baby. Your doctor will decide if you can use Benlysta.
- **If you become pregnant** while being treated with Benlysta, tell your doctor.

**Breast-feeding**

**Tell your doctor if you are breast-feeding.** It is likely that Benlysta can pass into breast milk. Your doctor will discuss with you whether you should stop treatment with Benlysta while you are breast-feeding, or if you should stop breast-feeding.

**Driving and using machines**
Benlysta can have side effects which may make you less able to drive or use machines.

**Benlysta contains polysorbate 80**
This medicine contains 0.1 mg of polysorbate 80 in each pre-filled pen. Polysorbates may cause allergic reactions. Tell your doctor if you have or your child has any known allergies.

**Benlysta contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per dose, so it is essentially 'sodium-free'.

## 3. How Benlysta is used

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

Benlysta must be injected under your skin following the schedule prescribed to you by your doctor.

**How much to use**

*Systemic lupus erythematosus*

*Adults*
**The recommended dose is** 200 mg (complete contents of one pen) once a week.

*Children and adolescents 5 years and older*
The recommended dose for children and adolescents 5 years and older is based on weight as shown below:

| Body weight | Recommended dose |
|---|---|
| 50 kg or more | 200 mg (complete contents of one pen) once a week |
| 30 kg to less than 50 kg | 200 mg (complete contents of one pen) once every 10 days |
| 15 kg to less than 30 kg | 200 mg (complete contents of one pen) once every 2 weeks |

*Lupus nephritis*

*Adults only*

**The recommended dose may vary.** Your doctor will prescribe the right dose for you, which is either:

- a dose of 200 mg (complete contents of one pen) once a week.

**or**

- a dose of 400 mg (complete contents of two pens in one day) once a week for 4 weeks. After this, the recommended dose is 200 mg (complete contents of one pen) once a week.

**If you wish to change your dosing day**
Take a dose on the new day (even if the time since your last dose is less than usual). Continue with the new schedule from that day.

**Injecting Benlysta**
Your doctor or nurse will show you or your caregiver how to inject Benlysta. Your first injection with the Benlysta pre-filled pen will be supervised by your doctor or nurse. After you have been trained on how to use the pen, your doctor or nurse may decide that you can give yourself the injection, or your caregiver can give it to you. Your doctor or nurse will also tell you what signs and symptoms to look out for when using Benlysta, because serious allergic reactions can occur (see *'Allergic reactions'* in section 4).

For children under 10 years of age, the Benlysta pre-filled pen must be injected by a doctor, nurse, or trained caregiver.

You inject Benlysta under your skin in your stomach area (abdomen) or upper leg (thigh).

Benlysta subcutaneous injection must not be injected into a vein (*intravenously*).

Instructions for using the pre-filled pen are given at the end of this leaflet.

**If you use more Benlysta than you should**
If this happens, immediately contact your doctor or nurse, who will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary. If possible show them the pack, or this leaflet.

**If you forget to use Benlysta**
Inject the missed dose as soon as you remember. Then continue with your normal weekly schedule as usual or start a new weekly schedule starting from the day you inject the missed dose.
If you do not notice that you have missed a dose until it is already time for your next dose, then just inject this next dose as planned.

**Stopping treatment with Benlysta**
Your doctor will decide if you need to stop using Benlysta.

## 4. Possible side effects

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

**Stop using Benlysta and seek medical attention immediately** if you notice any of the following symptoms of a severe skin reaction:

- reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These severe skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome and toxic epidermal necrolysis). These side effects have been reported with unknown frequency (cannot be estimated from the available data).

**Allergic reactions — get medical help immediately**
Benlysta can cause a reaction to the injection, or an allergic *(hypersensitivity)* reaction.
These are common side effects (may affect up to 1 in 10 people). They can occasionally be severe (uncommon, affecting up to 1 in 100 people), and could be life-threatening. These severe reactions are more likely to happen on the day of your first or second treatment with Benlysta, but can be delayed and occur several days afterwards.

**Tell your doctor or nurse immediately,** or **go to the Emergency department of your nearest hospital, if you get any of the following symptoms of an allergic or injection-related reaction:**

- swelling of the face, lips, mouth or tongue
- wheezing, difficulty in breathing or shortness of breath
- rash
- itchy raised bumps or hives.

Rarely, less severe delayed reactions to Benlysta can also occur, usually 5 to 10 days after an injection. They include symptoms such as rash, feeling sick, tiredness, muscle aches, headache, or facial swelling.
**If you experience these symptoms,** particularly if you get two or more of them together:

➔ **Tell your doctor or nurse.**

**Infections**
Benlysta can make you more likely to get infections, including infection of the urinary tract and airways. These are very common and may affect more than 1 in 10 people. Some infections can be severe and can uncommonly cause death.

**If you get any of the following symptoms of an infection:**

- fever and/or chills
- cough, breathing problems
- diarrhoea, vomiting
- burning sensation while passing urine; urinating often
- warm, red or painful skin or sores on your body.

➔ **Tell your doctor or nurse immediately.**

**Depression and suicide**
There have been reports of depression, suicidal thoughts, and suicide attempts during treatment with Benlysta. Depression can affect up to 1 in 10 people, suicidal thoughts and suicide attempts can affect up to 1 in 100 people. If you feel depressed, have thoughts about harming yourself or other distressing thoughts, or if you are depressed and notice that you feel worse or develop new symptoms:

➔ **Contact your doctor or go to a hospital straight away.**

**Increased risk of brain infection**
Medicines that weaken your immune system, such as Benlysta, may put you at higher risk of getting a rare but serious and life-threatening brain infection called *progressive multifocal leukoencephalopathy* (PML).

**Symptoms** of PML include:

- memory loss
- trouble in thinking
- difficulty with talking or walking

- loss of vision.
  - ➔ **Tell your doctor immediately** if you have any of these symptoms, or similar problems that have lasted over several days.

If you already had these symptoms before you started treatment with Benlysta:
- ➔ **Tell your doctor immediately** if you notice any changes in these symptoms.

**Other possible side effects:**

**Very common side effects**
These may affect **more than 1 in 10** people:
- bacterial infections *(see 'Infections' above)*.

**Common side effects**
These may affect **up to 1 in 10** people:
- high temperature or fever
- injection site reactions, for example: rash, redness, itching or swelling of the skin where you have injected Benlysta
- itchy, bumpy rash (hives), skin rash
- low white blood cell count (can be seen in blood tests)
- nose, throat or stomach infection
- pain in hands or feet
- migraine
- feeling sick, diarrhoea

**Reporting of side effects**
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Benlysta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton 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.

Store in the original package in order to protect from light.

A single Benlysta pre-filled pen can be stored at room temperature (up to 25°C) for a maximum of 12 hours – as long as it is protected from light. Once removed from the refrigerator, the pen **must be used within 12 hours or discarded**.

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 Benlysta contains**
The active ingredient is belimumab.

Each 1 mL pre-filled pen contains 200 mg belimumab.

The other ingredients are arginine hydrochloride, histidine, histidine monohydrochloride, polysorbate 80 (E 433), sodium chloride, water for injection. See section 2 for further information on polysorbate 80 and sodium content.

**What Benlysta looks like and contents of the pack**
Benlysta is supplied as a 1 mL colourless to slightly yellow solution in a single use pre-filled pen.

Available in packs of 1 or 4 pre-filled pens in each pack and multipacks comprising 12 pre-filled pens (3 packs of 4 pre-filled pens).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

GlaxoSmithKline UK Limited
79 New Oxford Street
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WC1A 1DG
United Kingdom

**Manufacturer**

Glaxo Operations UK Ltd
Harmire Road
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OR

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**Other formats**
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only)

Please be ready to give the following information:

**Product name – Benlysta 200 mg solution for injection in pre-filled pen**
Reference number – 19494/0271

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in January 2026**

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**Step-by-step instructions for using the pre-filled pen**

**Once weekly:** for adults, and for children 5 to under 18 years of age and weighing 50 kg or more.

**Once every 10 days:** for children 5 to under 18 years of age and weighing 30 kg to less than 50 kg.

**Once every 2 weeks:** for children 5 to under 18 years of age and weighing 15 kg to less than 30 kg.

**Read These Sections First**

Follow these instructions on how to use the pre-filled pen correctly. Failure to follow these instructions may affect proper function of the pre-filled pen. You will also need to receive training on how to use the pre-filled pen.

Benlysta is for use **under the skin only** (*subcutaneous*).

To improve the traceability of this medicine, you and your healthcare provider should record the Benlysta lot number. It is recommended that you make a note of this information in case you are asked for it in the future.

**Storage**

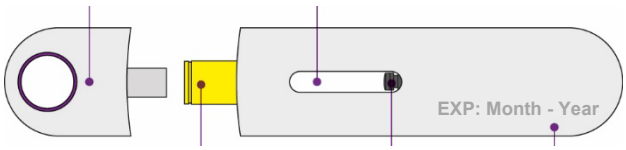
- Keep refrigerated until 30 minutes before use.
- Keep in the carton in order to protect from light.
- Keep out of the sight and reach of children.
- Keep away from heat and sunlight.
- **Do not** freeze. If the pen has been frozen, **do not** use the pen even if it is thawed.
- **Do not** use and **do not** place back in the refrigerator if left out at room temperature for more than 12 hours.

**Warnings**

- The pre-filled pen must only be used once and then discarded.
- **Do not** share your Benlysta pre-filled pen with another person.
- **Do not** shake.
- **Do not** use if dropped onto a hard surface.
- **Do not** remove the ring cap until just before the injection.

**Benlysta pre-filled pen parts**

**Ring cap** **Inspection window**

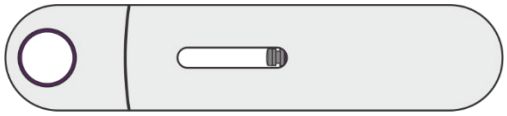



**Gold needle guard**
(needle inside)

**Grey stopper**

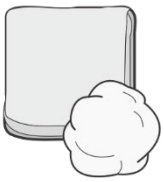
**Expiry date**

**Supplies you need for the injection**



**Benlysta pre-filled pen**

**Alcohol swab**
*(not included)*



**Gauze pad or cotton wool ball**
*(not included)*

**1. Gather and check supplies**

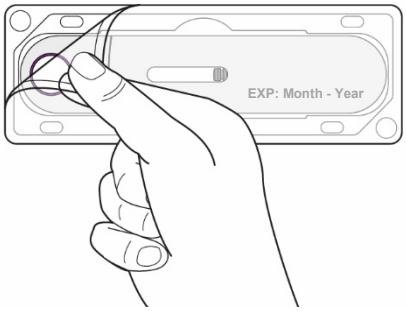
**Gather supplies**

- Remove one sealed tray containing a pre-filled pen from the refrigerator.
- Place any remaining pre-filled pens back into the refrigerator.
- Find a comfortable, well-lit and clean surface and place the following supplies within reach:
  - Benlysta pre-filled pen
  - alcohol swab (*not included in the pack*)
  - gauze pad or cotton wool ball (*not included in the pack*)
  - container with a tight-fitting lid for pen disposal (*not included in the pack*).
- **Do not** perform the injection if you do not have all the supplies listed.

**Take out the pre-filled pen**

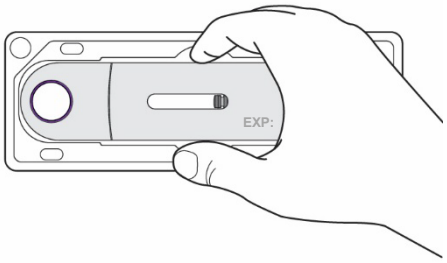
- Peel back the film from the corner of the tray. (*Figure 1*)

*Figure 1*




- Holding the middle of the pre-filled pen (near the inspection window), carefully take the pre-filled pen out of the tray. (*Figure 2*)

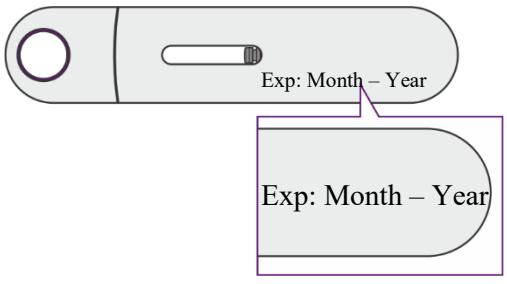
*Figure 2*




**Check the expiry date**

- Check the expiry date on the pre-filled pen. (*Figure 3*)

*Figure 3*




- **Do not** use if the expiry date has passed

**2. Prepare and inspect the pre-filled pen**

**Allow to come to room temperature**

- Leave the pen at room temperature for 30 minutes. (*Figure 4*) Injecting cold Benlysta may take longer and may be uncomfortable.

*Figure 4*

- **Do not** warm the pen in any other way. For example, do not warm it in a microwave oven, hot water or direct sunlight.

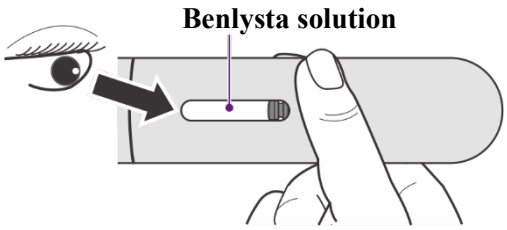
- **Do not** remove the ring cap during this step.

**Inspect the Benlysta solution**

- Look in the inspection window to check that the Benlysta solution is colourless to slightly yellow in colour. (*Figure 5*)

    - It is normal to see one or more air bubbles in the solution.

*Figure 5*



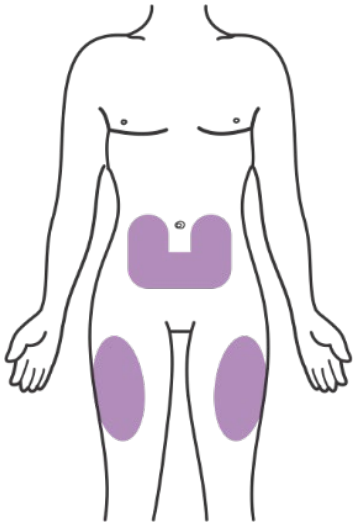

- **Do not** use if the solution looks cloudy, discoloured or has particles.

**3. Choose and clean the injection site**

**Choose the injection site**

- Choose an injection site (abdomen or thigh) as seen in *Figure 6*.

*Figure 6*

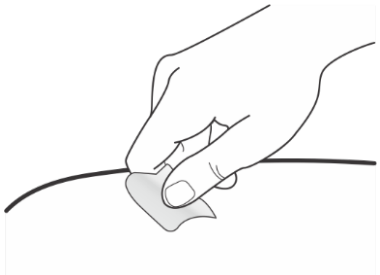


- If you need 2 injections to complete your dose, leave at least 5 cm (2 inches) between each injection if using the same site.
- **Do not** inject into the exact same site each time. This is to avoid the skin becoming hardened.
- **Do not** inject in areas where the skin is tender, bruised, red or hard.
- **Do not** inject within 5 cm (2 inches) of the navel (belly button).

**Clean the injection site**

- Wash your hands.
- Clean the injection site by wiping it with an alcohol swab (*Figure 7*). Allow the skin to air dry.

*Figure 7*



- **Do not** touch this area again before giving the injection.

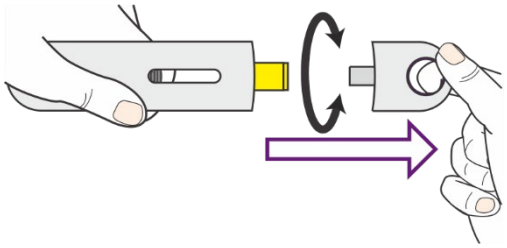
**4. Prepare for the injection**

**Remove the ring cap**

- **Do not** remove the ring cap until immediately before the injection.

- Remove the ring cap by pulling or twisting it off. The ring cap may be twisted off either clockwise or anti-clockwise. (*Figure 8*)

*Figure 8*

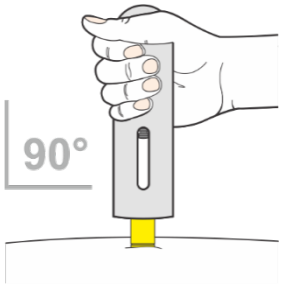


- **Do not** put the ring cap back onto the pen.

**Position the pen**

- Hold the pen comfortably so that you can view the inspection window. This is important so that you can confirm a complete dose. (*Figure 9*)

*Figure 9*



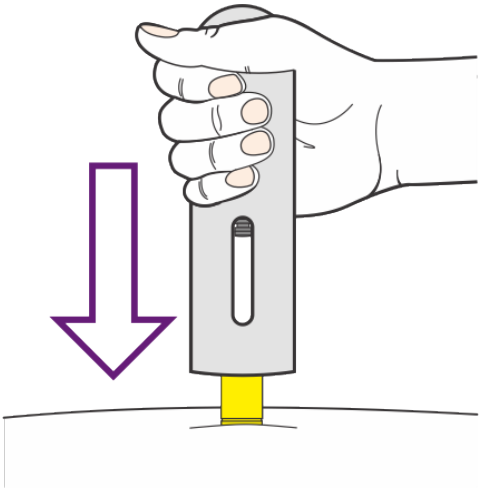

- If needed, firm the injection site by pulling or stretching the skin.
- Position the pen straight over the injection site (at a 90º angle). Make sure the gold needle guard is flat on the skin.

**5. Inject Benlysta and Inspect**

**Start the injection**

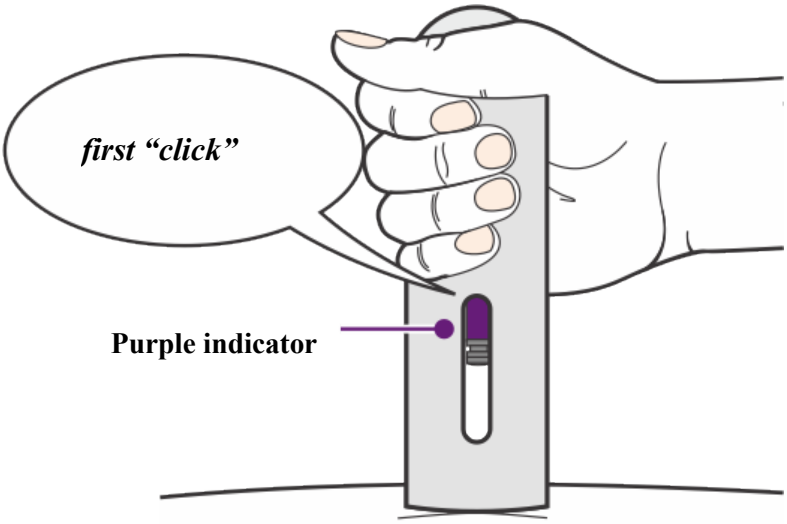
- Firmly press the pen all the way down onto the injection site and hold in place. (*Figure 10*)
- This will insert the needle and start the injection.

*Figure 10*



- You may hear a first “click” at the start of the injection. You will see the purple indicator start to move through the inspection window. (*Figure 11*)

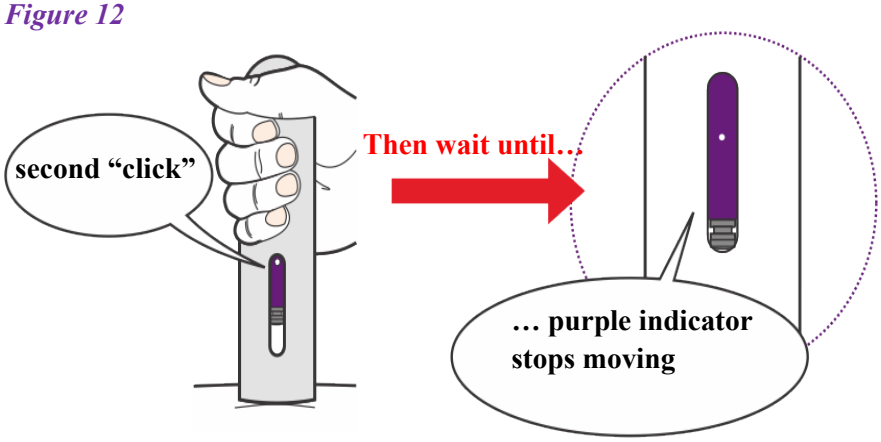
*Figure 11*




**Complete the injection**

- Continue to hold the pen down until the purple indicator has stopped moving. You may hear a second “click” a few seconds before the purple indicator stops moving. (*Figure 12*)

*Figure 12*




- The injection may take up to 15 seconds to complete.
- When the injection is complete, lift the pen from the injection site.

**Inspect the injection site**

There may be a small amount of blood at the injection site.

- If needed, press a cotton ball or gauze pad on the injection site.
- **Do not** rub the injection site

**6. Dispose of used pen**

**Dispose of the used pen**

- Do not put the ring cap back onto the pen.
- Dispose of the used pen and ring cap in a container with a tight-fitting lid.
- Ask your doctor or pharmacist for instructions on how to properly dispose of a used pen or container of used pens.
- **Do not** recycle or throw the used pen, or the container of used pens, in household waste.