

## **Package leaflet: Information for the user**

### **STEQEYMA 45 mg solution for injection in pre-filled pen** 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.**

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

#### **1. What Steqeyma is and what it is used for**

##### **What Steqeyma is**

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

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

##### **What Steqeyma is used for**

Steqeyma administered using the pre-filled pen is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults
- Moderate to severe ulcerative colitis - in adults

##### **Plaque psoriasis**

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

Steqeyma administered using the pre-filled pen is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, 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 Steqeyma 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 Steqeyma 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 Steqeyma to reduce the signs and symptoms of your disease.

## **2. What you need to know before you use Steqeyma**

### **Do not use Steqeyma**

- **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 Steqeyma.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Steqeyma. 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 Steqeyma. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

### **Look out for serious side effects**

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

### **Before you use Steqeyma 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 Steqeyma 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 ustekinumab 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 ustekinumab 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 Steqeyma.

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**

The Steqeyma pre-filled pen is not recommended for use in children and adolescents under 18 years of age with psoriasis or Crohn's disease because it has not been studied in this age group. The pre-filled syringe or vial should be used instead for children 6 years of age and older and adolescents with psoriasis. The solution for infusion, pre-filled syringe or vial should be used instead for children weighing at least 40 kg with Crohn's disease.

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

### **Other medicines, vaccines and Steqeyma**

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 Steqeyma.
- If you received Steqeyma while pregnant, tell your baby's doctor about your Steqeyma 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 Steqeyma 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 Steqeyma in pregnancy.
- If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Steqeyma and for at least 15 weeks after the last Steqeyma treatment.
- Ustekinumab can pass across the placenta to the unborn baby. If you received Steqeyma 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 Steqeyma 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 Steqeyma 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 Steqeyma - do not do both.

### **Driving and using machines**

Steqeyma has no or negligible influence on the ability to drive and use machines.

### **Steqeyma contains polysorbate 80**

Steqeyma contains 0.02 mg of polysorbate 80 (E433) 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 Steqeyma**

Steqeyma is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Steqeyma 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 Steqeyma is given**

Your doctor will decide how much Steqeyma 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 Steqeyma. 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 Steqeyma 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 Steqeyma 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 Steqeyma may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

### **How Steqeyma is given**

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

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

### **If you use more Steqeyma than you should**

If you have used or been given too much Steqeyma, 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 Steqeyma**

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 Steqeyma**

It is not dangerous to stop using Steqeyma. 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 Steqeyma 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)

Steqeyma 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 Steqeyma. 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 Steqeyma 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 Steqeyma**

- 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 pen in the outer carton in order to protect from light.

- If needed, individual Steqeyma pre-filled pens may also be stored at room temperature up to 25 °C for a maximum single period of up to 31 days in the original carton in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator in the space provided on the outer carton. At any time before the end of this 31-day period at room temperature, the product can be returned to the refrigerator once, and stored there until the original expiry date. Discard the pen if not used within 31 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake Steqeyma pre-filled pens. 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 other foreign particles floating in it (see section 6 'What Steqeyma 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.

Steqeyma is for single use only. Any unused product remaining in the pre-filled pen 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 Steqeyma contains**

- The active substance is ustekinumab. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 (E433), sucrose and water for injections.

### **What Steqeyma looks like and contents of the pack**

Steqeyma is a clear to slightly opalescent (having a pearl-like shine), colourless to pale yellow solution for injection. The solution may contain a few small translucent or white particles of protein. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled pen. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL of solution for injection.

### **Marketing Authorisation Holder**

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## Instructions for administration

At the start of treatment, your healthcare provider will assist you with your first injection. However, you and your doctor may decide that you may inject Steqeyma yourself. If this happens, you will get training on how to inject Steqeyma. Talk to your doctor if you have any questions about giving yourself an injection.

## Important Information

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- Use the pre-filled pen **only if** your healthcare provider has trained you on the right way to prepare for and to give an injection. **Do not try to inject yourself until you have been trained by your doctor.**
- **Do not reuse the pre-filled pen.**
- **Do not** open the sealed carton until you are ready to use the pre-filled pen.
- **Do not** remove the cap until just before you give the injection.
- **Do not** mix Steqeyma with other liquids for injection.
- **Do not** use if the pre-filled pen is cracked or damaged.
- **Do not** use the medicine if the expiration date has passed.
- **Do not** share the pre-filled pen with anyone.
- The pre-filled pen cannot be re-used. Dispose of the used pre-filled pen immediately after use in a sharps disposal container (see **Step 15. Dispose of the pre-filled pen**).

## Storing the pre-filled pen

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- **Keep the pre-filled pen out of the sight and reach of children.** This product contains small parts.
- Store the pre-filled pen in a refrigerator between 2°C and 8°C.
- **Do not** freeze the pre-filled pen.
- If needed, individual Steqeyma pre-filled pens may also be stored at room temperature up to 25°C for a maximum single period of up to 31 days in the original carton in order to protect from light.
- Record the date when the pre-filled pens are first removed from the refrigerator in the spaces provided on the outer carton.
- At any time before the end of the storage period at room temperature, the product can be returned to the refrigerator **once**, and stored there until the original expiry date.
- Store this medicine sealed inside its carton to protect it from light.
- **Do not** use the pre-filled pen if it has been left in direct sunlight.
- **Do not** shake Steqeyma pre-filled pens. Strong shaking may damage the medicine.
- **Do not** use the medicine if it has been shaken.
- **Do not** use if the pre-filled pen has been dropped on a hard surface.
- Always keep the pre-filled pen dry.

## Parts of the Steqeyma pre-filled pen (see Figure A)

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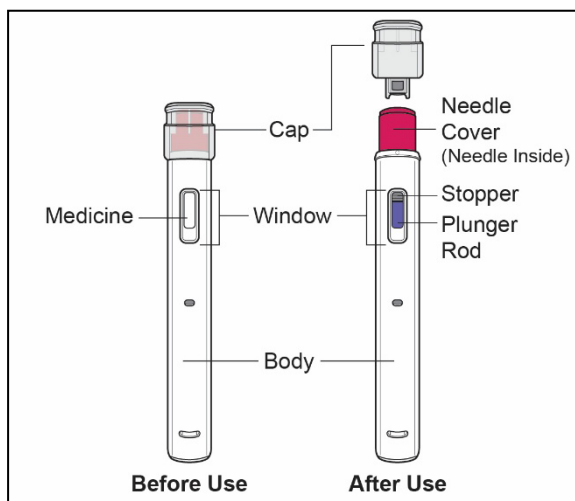


Figure A

## Preparing for the Injection

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### 1. Gather the supplies for the injection.

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- Remove the carton(s) containing the pre-filled pen(s) from your refrigerator.
  - Depending on the dose prescribed to you by your healthcare provider you may need to prepare one or more pre-filled pens and inject the contents of them all.
- Make sure you have the following supplies (see **Figure B**):
  - Carton containing pre-filled pen

#### Not included in the carton:

- Cotton ball or gauze
- Alcohol swab
- Adhesive bandage
- Sharps disposal container

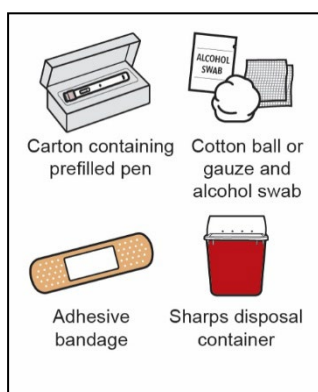
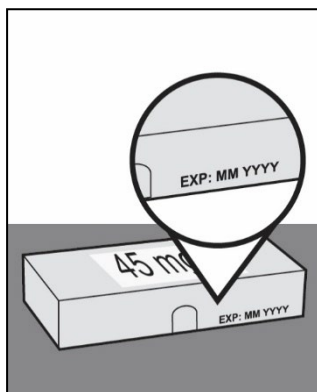


Figure B

### 2. Check the expiration date on the carton (see Figure C).

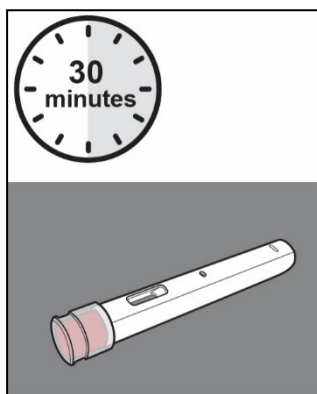
- Do not** use it if the expiration date has passed. If the expiration date has passed, return the entire pack to the pharmacy.



**Figure C**

### **3. Wait 30 minutes.**

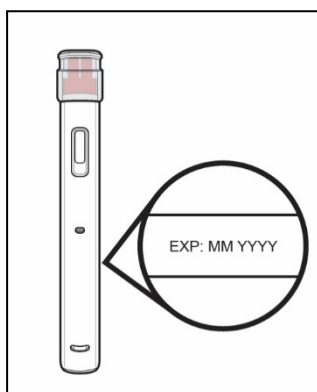
- a. Open the carton and remove the pre-filled pen.
- b. Leave the pre-filled pen at room temperature (20°C to 25°C) for about 30 minutes to allow it to warm up (see **Figure D**).
  - This will let the liquid come to a comfortable temperature for injection (room temperature).
  - **Do not** warm the pre-filled pen using heat sources such as hot water or a microwave.



**Figure D**

### **4. Inspect the pre-filled pen.**

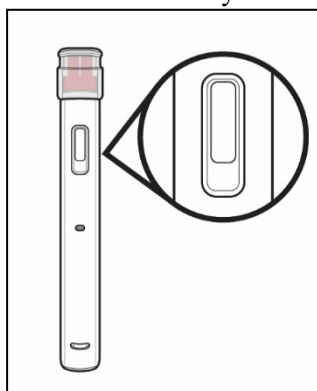
- a. Look at the pre-filled pen and make sure you have the correct medicine (Steqeyma) and dosage.
- b. Check the pre-filled pen(s) to make sure the number of pre-filled pens is correct:
  - if your dose is 45 mg you will get one 45 mg pre-filled pen of Steqeyma.
  - **if your dose is 90 mg you will get two 45 mg pre-filled pens of Steqeyma and you will need to give yourself two injections.** Choose two different sites for these injections (e.g. one injection in the right thigh and the other injection in the left thigh), and give the injections one right after the other.
- c. Look at the pre-filled pen and make sure it is not cracked or damaged.
- d. Check the expiration date on the label of the pre-filled pen (see **Figure E**).
  - **Do not** shake the pre-filled pen.
  - **Do not** use the pre-filled pen if:
    - it has been dropped onto a hard surface.
    - it has been cracked or damaged.
    - the expiration date has passed.



**Figure E**

**5. Inspect the medicine.**

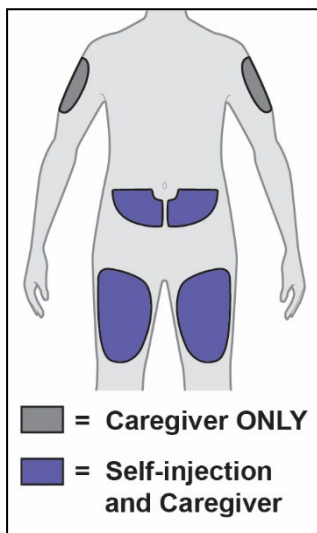
- a. Look at the medicine and confirm that the liquid is clear to slightly opalescent, colourless to pale yellow (see **Figure F**).
  - **Do not** use the pre-filled pen if the liquid is discoloured, cloudy, or has large particles.
    - You may see air bubbles in the liquid. This is normal.



**Figure F**

**6. Choose an injection site (see Figure G):**

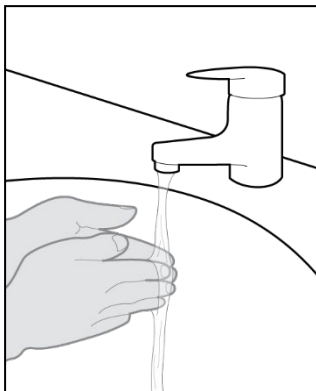
- a. You may inject into:
  - the front of your upper thighs.
  - your lower abdomen except for the 5 cm around the belly button (navel).
  - the outer area of the upper arm if you are a caregiver.
  - **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard, or if there are breaks in the skin. If possible, **do not** use areas of skin that show signs of psoriasis.
  - **Do not** inject through your clothes.
- b. Choose a different injection site for each new injection at least 2.5 cm away from the area used for the last injection.



**Figure G**

**7. Wash your hands.**

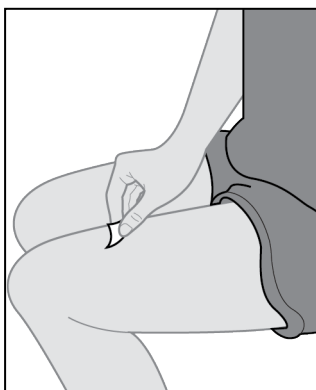
- a. Wash your hands with soap and water and dry them thoroughly (see **Figure H**).



**Figure H**

**8. Clean the injection site.**

- a. Clean the injection site with an alcohol swab using a circular motion (see **Figure I**).
- b. Let the skin dry before injecting.
  - **Do not** blow on or touch the injection site again before giving the injection.



**Figure I**

**Administering the Injection**

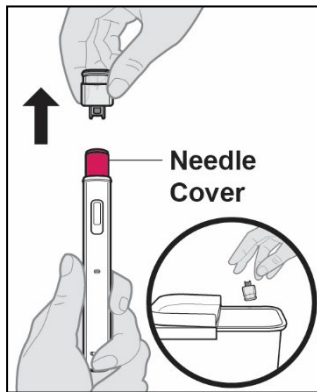
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**9. Remove the cap**

- a. Hold the pre-filled pen in one hand by the injector body with the cap on top. Gently pull the cap straight off with the other hand (see **Figure J**).

- **Do not** remove the cap until you are ready to inject.
  - It is normal to see a few drops of liquid come out of the needle.
- **Do not** touch the needle or needle cover. Doing so may result in a needle stick injury because the needle is inside the needle cover.
  - **Inject STEQEYMA within 5 minutes of removing the cap.**
- **Do not** re-cap the pre-filled pen.

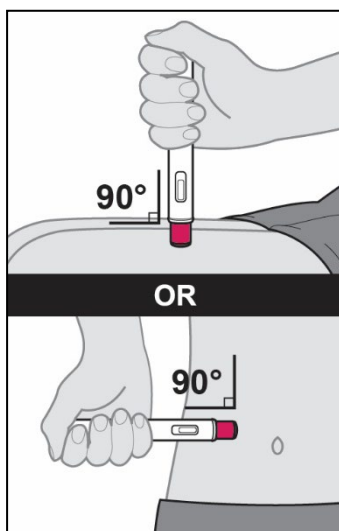
b. Dispose of the cap right away in a sharps disposal container (see **Step 15** and **Figure J**).



**Figure J**

**10. Place the pre-filled pen on the injection site.**

- Hold the pre-filled pen so that you can see the window.
- Without pinching or stretching the skin, place the pre-filled pen over the injection site at a 90-degree angle (see **Figure K**).



**Figure K**

**11. Give the injection.**

- Press the pre-filled pen **firmly** against the skin. When the injection starts you will hear the 1<sup>st</sup> “click” and the light lila plunger rod will begin to fill the window (see **Figure L**).
- Keep holding the pre-filled pen **firmly** against the skin and listen for the 2<sup>nd</sup> “click” (see **Figure L**).
  - **Do not** change the position of the pre-filled pen after the injection has started.
- After you hear the 2<sup>nd</sup> “click,” continue to hold the pre-filled pen **firmly** against the skin and **count slowly to 5** to make sure you inject the full dose.

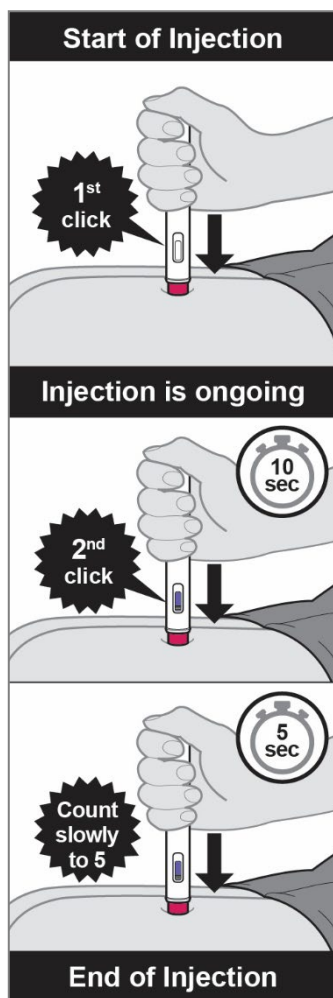


Figure L

**12. Remove the pre-filled pen from the injection site.**

- a. Look at the pre-filled pen and make sure that the light lila plunger rod with the grey stopper is filling the window completely.
  - You may see the grey stopper in the window. This is normal.
  - If the window has not turned completely light lila or if the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.
- b. Remove the pre-filled pen from your skin (see **Figure M**).
  - After you remove the pre-filled pen from the injection site, the needle will be automatically covered (see **Figure N**). **Do not** re-cap the pen.
  - **Do not** reuse the pre-filled pen.
  - **Do not** rub the injection site.

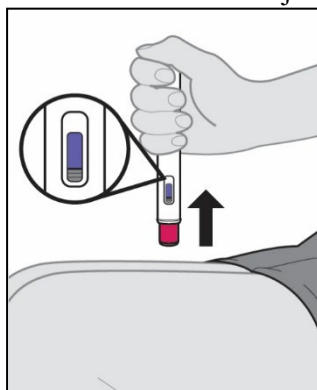
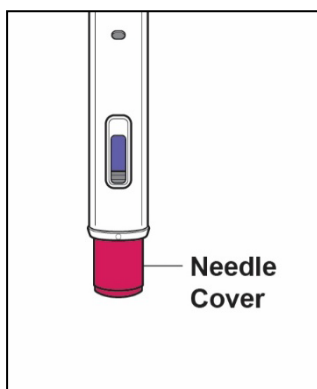


Figure M



**Figure N**

**13. If your dose requires 2 injections, inject second dose.**

- a. If you receive two 45 mg pre-filled pens for a 90 mg dose, immediately repeat **Steps 5-12**.
  - Give the injections one right after the other.
  - **Choose a different site for the second injection.**

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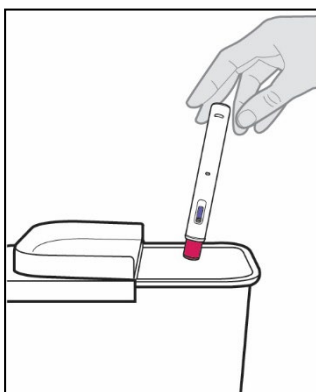
**After the Injection**

**14. Care for the injection site.**

- a. If some bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.

**15. Dispose of the pre-filled pen.**

- **Do not** re-cap the pre-filled pen.
- a. Throw away the used pre-filled pen in a sharps disposal container as instructed by your doctor, nurse or pharmacist (see **Figure O**).
- b. The alcohol swab and packaging may be put in your household trash.
- **Do not** throw away (dispose of) the pre-filled pen in your household trash.
  - If you do not have a sharps disposal container, you may use a household container that is:
    - made of a heavy-duty plastic,
    - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
    - upright and stable during use,
    - leak-resistant, and
    - properly labeled to warn of hazardous waste inside the container.



**Figure O**