

## Package leaflet: Information for the user

### STEQEYMA 90 mg solution for injection in pre-filled syringe ustekinumab

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

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

**This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give Steqeyma to a child, please read this information carefully.**

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

#### What is in this leaflet

1. What 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 is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults and children aged 6 years and older
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults

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

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

### **Psoriatic arthritis**

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given 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.

## **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**

Steqeyma is not recommended for use in children with psoriasis under 6 years of age, or for use in children under 18 years of age with psoriatic arthritis, or Crohn's disease 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 six months after birth if you received Steqeyma during the pregnancy unless your baby's doctor recommends otherwise.

### **Pregnancy and breast-feeding**

- It is preferable to avoid the use of Steqeyma in pregnancy. The effects of ustekinumab in pregnant women are not known. 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.
- Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- 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 six 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.

## **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**

- 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.

### **Children and adolescents aged 6 years or older**

#### **Psoriasis**

There is no dosage form for Steqeyma for children with plaque psoriasis below 60 kg body weight and therefore other ustekinumab products should be used.

- The doctor will work out the right dose for you, including the amount (volume) of Steqeyma to be injected to give the right dose. The right dose for you will depend on your body weight at the time each dose is given.
- If you weigh less than 60 kg, there is no dose form of Steqeyma available and other ustekinumab products should be used.
- If you weigh 60 kg to 100 kg, the recommended dose is 45 mg Steqeyma.
- If you weigh more than 100 kg, the recommended dose is 90 mg Steqeyma.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks.

### **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 syringe in the outer carton in order to protect from light.
- If needed, individual Steqeyma pre-filled syringes may also be stored at room temperature up to 30 °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 syringe is first removed from the refrigerator and

the discard date in the space provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature (up to 30 °C), it should not be returned to the refrigerator. Discard the syringe if not used within 31 days at room temperature storage or by the original expiry date, whichever is earlier.

- Do not shake Steqeyma pre-filled syringes. Prolonged vigorous shaking may damage the medicine.

**Do not use this medicine:**

- After the expiry date which is stated on the label and the carton after ‘EXP’. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see 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 syringe should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Steqeyma contains**

- The active substance is ustekinumab. Each pre-filled syringe contains 90 mg ustekinumab in 1 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, 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 syringe. Each pre-filled syringe contains 90 mg ustekinumab in 1 mL of solution for injection.

### **Marketing Authorisation Holder**

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### **Manufacturer**

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### **United Kingdom**

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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

- **Do not** open the sealed carton until you are ready to use the pre-filled syringe.
- **Do not** remove the cap until just before you give the injection.
- **Do not** mix Steqeyma with other liquids for injection.
- The pre-filled syringe cannot be re-used. Dispose of the used pre-filled syringe immediately after use in a sharps disposal container (see **Step 14. Dispose of Steqeyma**).

### Storing Steqeyma

- **Keep the pre-filled syringe out of the sight and reach of children.** Contains small part.
- Store the pre-filled syringe in a refrigerator between 2°C and 8°C. **Do not** freeze.
- Store this medicine sealed inside its carton to protect it from light.
- If needed, individual Steqeyma pre-filled syringes may also be stored at room temperature up to 30°C for a maximum single period of up to 31 days in the original carton in order to protect from light.
- **Do not** shake Steqeyma pre-filled syringes. Strong shaking may damage the medicine.
- **Do not** use the medicine if it has been shaken strongly.
- **Do not** use the pre-filled syringe if it has been dropped.

### Parts of the Pre-filled Syringe (see Figure A)

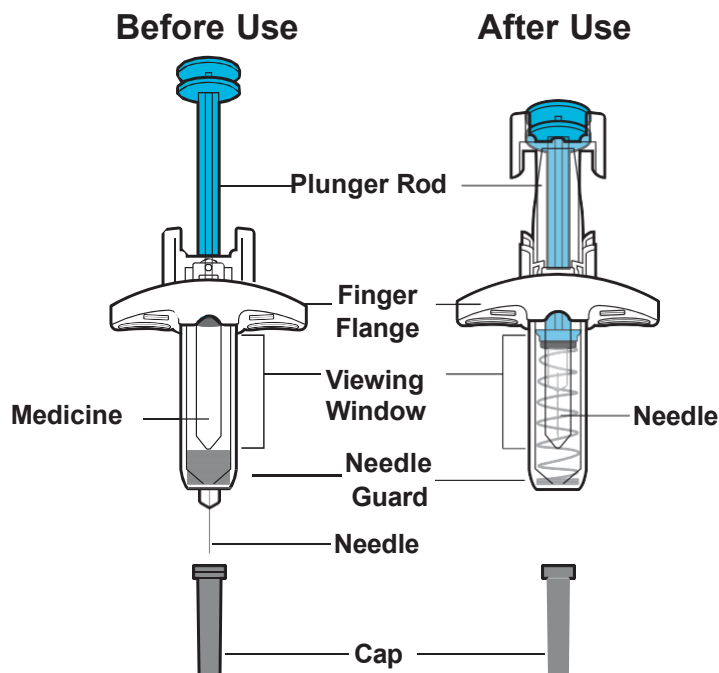
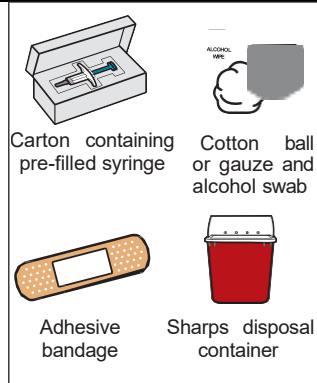


Figure A



## Preparing for the Injection



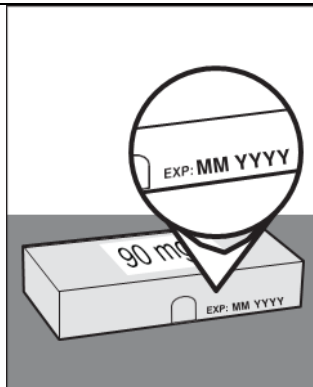
**Figure B**

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

- Prepare a clean, flat surface, such as a table or counter top, in a well-lit area.
- Take the carton(s) containing the pre-filled syringe(s) needed to administer your prescribed dose out of the refrigerator.
- Make sure you have the following supplies (see **Figure B**):
  - Carton containing pre-filled syringe

#### Not included in the carton:

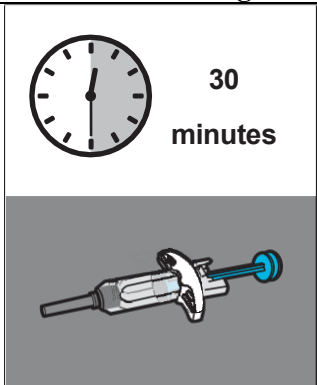
- Cotton ball or gauze
- Adhesive bandage
- Sharps disposal container
- Alcohol swab



**Figure C**

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

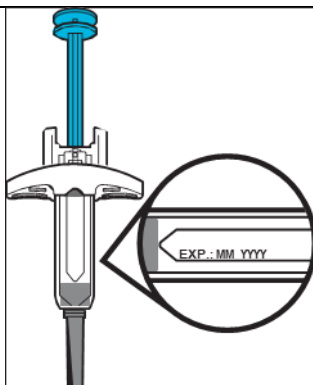
- **Do not** use it if the expiration date has passed. If the expiration date has passed, return the entire pack to the pharmacy.



**Figure D**

### 3. Wait 30 minutes.

- Open the carton. Gripping from the syringe body, lift the pre-filled syringe from the carton.
- Let the pre-filled syringe stand outside the box for about 30 minutes at room temperature (20 °C to 25 °C) to allow it to warm up (see **Figure D**).
  - **Do not** warm the pre-filled syringe using heat sources such as hot water or a microwave.
  - This will let the liquid come to a comfortable temperature for injection (room temperature).
  - **Do not** hold by the plunger head, plunger rod, needle guard wings, or needle cover
  - **Do not** pull back on the plunger rod at any time.



**Figure E**

### 4. Inspect the pre-filled syringe.

- Look at the pre-filled syringe and make sure you have the correct medicine (Steqeyma) and dosage.
- Check the pre-filled syringe(s) to make sure the number of pre-filled syringes and strength is correct:
  - If your dose is 90 mg you will get one 90 mg pre-filled syringe of Steqeyma.
- Look at the pre-filled syringe and make sure it is not cracked or damaged.
- Check the expiration date on the label of the pre-filled syringe (see **Figure E**).
  - **Do not** use if the expiration date has passed.
  - **Do not** shake the pre-filled syringe.

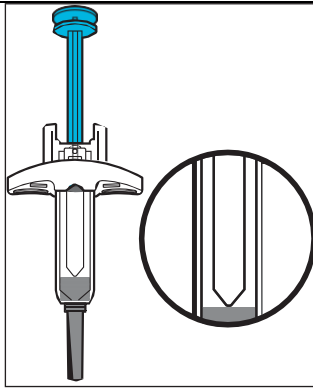


Figure F

**5. Inspect the medicine.**

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

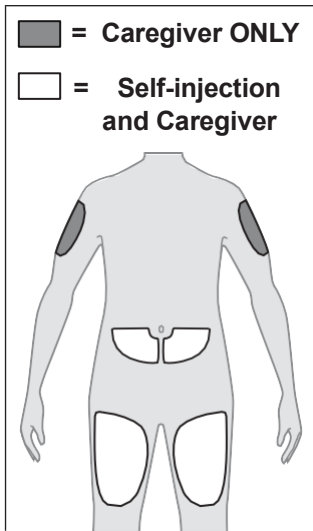


Figure G

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

- a. You may inject into:
  - 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.

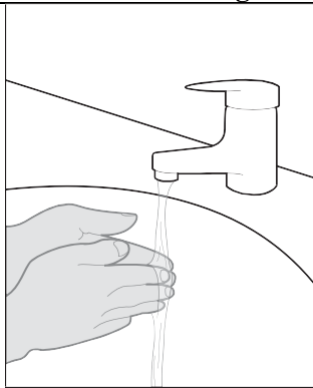


Figure H

**7. Wash your hands.**

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

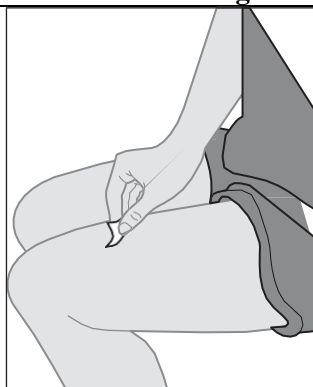


Figure I

**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.

## Administering the Injection

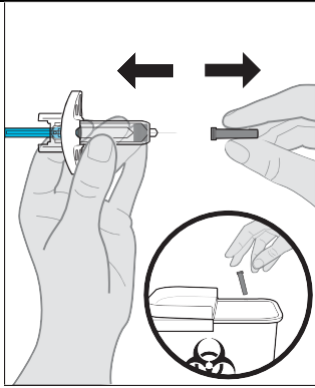


Figure J

### 9. Remove the cap.

- Remove the needle cover when you are ready to inject your Steqeyma by holding the body of the pre-filled syringe in one hand between the thumb and index fingers (see **Figure J**).
  - Do not** hold the plunger rod while removing the cap.
  - You may notice an air bubble in the pre-filled syringe or a drop of liquid at the tip of needle. This is normal.
- Dispose of the cap right away in a sharps disposal container (see **Step 14** and **Figure J**).
  - Do not** use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist.
  - Inject the dose promptly after removing the needle cover.
  - Do not** re-cap the pre-filled syringe.
  - Do not** touch the needle. Doing so may result in a needle stick injury.

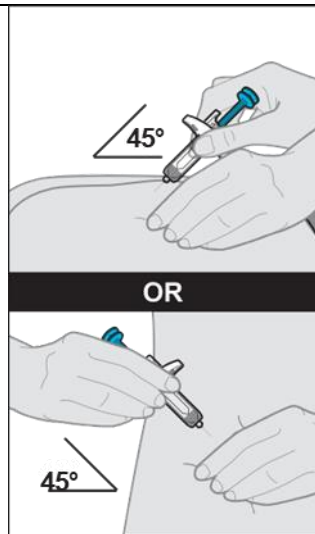


Figure K

### 10. Insert the pre-filled syringe into the injection site.

- Hold the body of the pre-filled syringe in one hand between the thumb and index fingers.
- Use the other hand to gently pinch the cleaned skin between your thumb and index finger. **Do not** squeeze it tightly.  
*Note:* Pinching the skin is important to make sure that you inject under the skin (into the fatty area) but not any deeper (into muscle).
- With a quick and dart-like motion, insert the needle completely into the fold of skin at a 45-degree angle (see **Figure K**).
  - Do not pull back on the plunger rod at any time.**

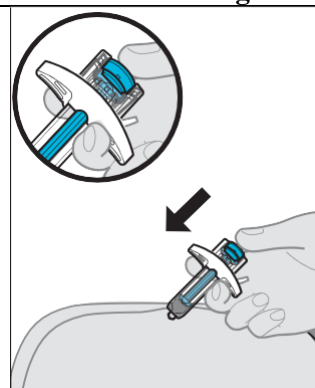


Figure L

### 11. Give the injection.

- After the needle is inserted, release the pinch.
- Slowly push the plunger rod **all the way down** until the full dose of medicine gets injected, and the syringe is empty (see **Figure L**).
  - Do not** change the position of the pre-filled syringe after the injection has started.
  - If the plunger rod is not fully pressed, the needle guard will not extend to cover the needle when it is removed.

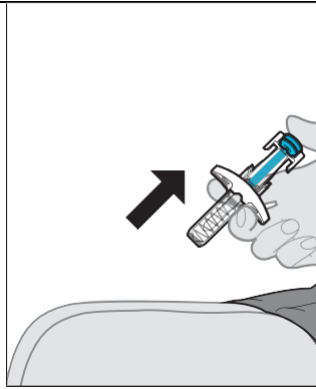


Figure M

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

- a. After the pre-filled syringe is empty, as the needle is being taken out, slowly remove the needle by lifting your thumb from the plunger rod until the needle is completely covered by the needle guard (see **Figure M**).
  - If the needle is not covered, proceed carefully to dispose of the syringe (see **Step 14. Dispose of Steqeyma**).
  - **Do not** reuse the pre-filled syringe.
  - **Do not** rub the injection site.

**After the Injection**

**13. 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.

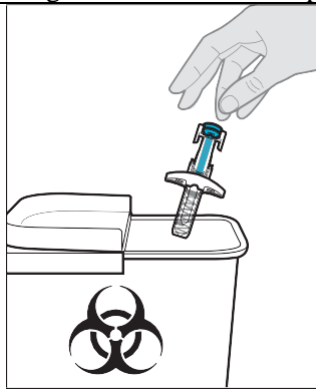


Figure N

**14. Dispose of Steqeyma.**

- a. Put the used pre-filled syringe in a sharps disposal container right away after use (see **Figure N**).
- b. Do not throw away (dispose of) the pre-filled syringe in your household trash.
  - If you do not have a sharps disposal container, you may use a household container that is closable and puncture resistant.
  - For the safety and health of you and others, needles and used syringes must never be reused. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
  - **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.