

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using STEQEYMA?

STEQEYMA contains the active ingredient ustekinumab. STEQEYMA is used in adults and paediatric patients (children and adolescents) 6 years and older with moderate to severe plaque psoriasis that is chronic (doesn't go away), adults with active psoriatic arthritis (an inflammatory disease of the joints that is usually accompanied by psoriasis), moderately to severely active Crohn's disease (an inflammatory disease of the bowel) and moderate to severe ulcerative colitis (an inflammatory disease of the bowel).

For more information, see Section [1. Why am I using STEQEYMA?](#) in the full CMI.

2. What should I know before I use STEQEYMA?

Do not use if you have ever had an allergic reaction to ustekinumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use STEQEYMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with STEQEYMA and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use STEQEYMA?

- STEQEYMA is injected under the skin (subcutaneous) More instructions can be found in Section [4. How do I use STEQEYMA?](#) in the full CMI.

5. What should I know while using STEQEYMA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using STEQEYMA.• Keep all your appointments.• Tell your doctor if you become pregnant and• If you or your baby is scheduled for any vaccines.
Things you should not do	<ul style="list-style-type: none">• Do not stop using STEQEYMA suddenly unless your doctor tells you to.• Do not receive a live vaccine while using STEQEYMA.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how STEQEYMA affects you. The effects on your ability to drive or use machines whilst taking STEQEYMA are not known.
Drinking alcohol	<ul style="list-style-type: none">• There is no information on the effects of taking STEQEYMA with alcohol
Looking after your medicine	<ul style="list-style-type: none">• Store at 2°C to 8°C. Refrigerate. Do not freeze.• Protect from light by storing in original carton until time of use. Do not shake.• If necessary, the diluted infusion solution may be stored for up to 48 hours at 2-8°C or eight hours at room temperature. Do not freeze. Discard any unused portion of the infusion solution.• If needed, you may store STEQEYMA pre-filled syringes and pre-filled pens at room temperature up to 25°C for one period of up to 31 days. Discard the syringe or pen if not used within 31 days at room temperature storage.• If needed, you may store STEQEYMA 45 mg/0.5 mL vial at room temperature up to 30°C for one period of up to 15 days. Discard the vial if not used within 15 days at room temperature storage.

For more information, see Section [5. What should I know while using STEQEYMA?](#) in the full CMI.

6. Are there any side effects?

Side effects that require urgent medical attention include: Signs of an allergic reaction, swollen face, lips, mouth or throat, cough, shortness of breath and fever.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

STEQEYMA[®] (Ste-QEY-ma)

Active ingredient: *ustekinumab (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using STEQEYMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using STEQEYMA.**

Where to find information in this leaflet:

- [1. Why am I using STEQEYMA?](#)
- [2. What should I know before I use STEQEYMA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use STEQEYMA?](#)
- [5. What should I know while using STEQEYMA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using STEQEYMA?

STEQEYMA contains the active ingredient **ustekinumab**. Ustekinumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind to other unique proteins.

Ustekinumab blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). IL-12 and IL-23 are made by your body's immune system. In people with psoriasis, psoriatic arthritis, and Crohn's disease or ulcerative colitis, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body. Ustekinumab can block IL-12 and IL-23 from causing the immune system to attack.

STEQEYMA is used in adults and paediatric patients (children and adolescents) 6 years and older with moderate to severe plaque psoriasis that is chronic (doesn't go away), adults with active psoriatic arthritis (an inflammatory disease of the joints that is usually accompanied by psoriasis), moderately to severely active Crohn's disease (an inflammatory disease of the bowel) and moderate to severe ulcerative colitis (an inflammatory disease of the bowel).

2. What should I know before I use STEQEYMA?

Warnings

Do not use STEQEYMA if:

- you are allergic to ustekinumab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have an infection.

Check with your doctor if you:

- have any kind of infection, even if it is very minor
- have an infection that won't go away or a history of infection that keeps coming back
- have had TB (tuberculosis), or if you have recently been near anyone who might have TB
- have or have had any type of cancer
- have any new or changing lesions within psoriasis areas or on normal skin
- recently received or are scheduled to receive a vaccine. **Patients receiving STEQEYMA should not receive live vaccines. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems**
- are receiving allergy immunotherapy

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Ask your doctor for advice before taking this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

STEQEYMA may be used during a pregnancy if needed. STEQEYMA may pass into your breastmilk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use STEQEYMA as it might be excreted in breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect STEQEYMA.

You should not receive a live vaccine while taking STEQEYMA. If you used STEQEYMA while pregnant, tell you baby's doctor about your STEQEYMA use before the baby receives any vaccines, including live vaccines, such as the BCG vaccines (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.

4. How do I use STEQEYMA?

How much to take / use

- For the treatment of psoriasis or psoriatic arthritis STEQEYMA is given by injection just under the skin (subcutaneously).
- For the treatment of Crohn's Disease and ulcerative colitis, the first dose of STEQEYMA will be given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. After this starting dose, all future doses of STEQEYMA are given by injection just under the skin (subcutaneously).
- All STEQEYMA injections are for single use in one patient only.
- STEQEYMA is intended for use under the guidance and supervision of your doctor. In children and adolescents 6 years and older with psoriasis, it is recommended that STEQEYMA be administered by a health care provider.
- When you start treatment, STEQEYMA may be injected by your healthcare provider. If your doctor determines that it is appropriate, you or your caregiver may be able to administer it under the skin yourself if you wish, after proper training in injection technique. (See How much to use and Injecting STEQEYMA under the skin yourself).
- It is important to remember that the first dose of STEQEYMA for the treatment of Crohn's Disease or ulcerative colitis (intravenous infusion) will always be administered by your healthcare provider.

How much to use

- Your doctor will determine the correct dose of STEQEYMA for you and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

For children and adolescents aged 6 years or older with psoriasis:

- 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, the recommended dose is 0.75 mg of STEQEYMA per kg body weight.
- 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.
- Follow the instructions provided and use STEQEYMA until your doctor tells you to stop.

How to use STEQEYMA

- STEQEYMA is injected under the skin (subcutaneous injection).
- It can be injected by the patient, or by someone else, such as a family member, friend or carer.
- Your first STEQEYMA injection may be administered by your healthcare provider. In children and adolescents 6 years and older, it is recommended that all doses of STEQEYMA be administered by a healthcare provider. However, your healthcare provider may decide that it is right for you or your caregiver to learn how to inject STEQEYMA under the skin (subcutaneously) yourself. If you would like to self-inject STEQEYMA under your skin, you or your caregiver 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 healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection.
- STEQEYMA is given alone and not mixed with other liquids for injection.

STEQEYMA should not be used:

- After the expiry date on the label,
- If the seal is broken,
- If the liquid is discoloured, cloudy or you can see other particulate matter floating in it,
- If you know, or think that it might have been exposed to extreme temperatures (such as being accidentally frozen or heated).

Do not shake STEQEYMA at any time.

- Prolonged vigorous shaking may damage the product. If STEQEYMA has been shaken vigorously, don't use it. STEQEYMA is not to be mixed with other liquids for injection.
- STEQEYMA injection under the skin (subcutaneous) is available in a vial, pre-filled syringe and pre-filled pen.
- 'Instructions for Use' for the vial, pre-filled syringe and pre-filled pen are provided below.
- STEQEYMA pre-filled pen is not intended for use in children below 6 years of age.

When to use STEQEYMA

- Follow the instructions provided and use STEQEYMA until your doctor tells you to stop.

STEQEYMA is available in a vial for intravenous infusion which will be administered by your healthcare provider.

STEQEYMA is also available in a vial, pre-filled syringe and pre-filled pen for injection under the skin (subcutaneous). Instructions for use for subcutaneous injections in vial, pre-filled syringe and pre-filled pen presentations are provided below.

How to inject STEQEYMA from a vial

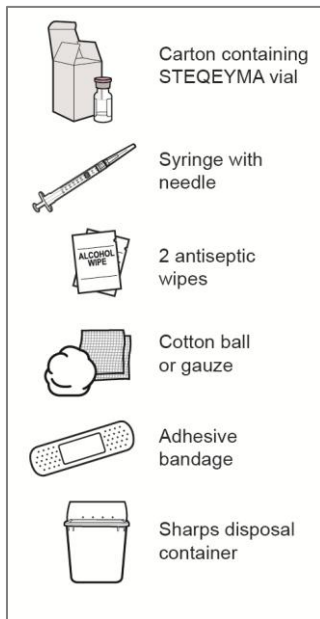


Figure A

1. **Gather the supplies for the injection.**
 - a. **Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.**
 - b. **Take the carton containing the STEQEYMA vial that is needed to administer your prescribed dose out of the refrigerator.**
 - c. **Make sure you have the following supplies (see Figure A):**
 - Carton containing the STEQEYMA vial
- Not included in the carton:**
- Syringe with needle
 - 2 alcohol swabs
 - Cotton ball or gauze
 - Adhesive bandage
 - Sharps disposal container

Note: If you don't know the syringe or needle needed contact your healthcare provider for further instructions.

2. **Check the expiration date on the carton (see Figure B).**
 - **Do not use the medication if the expiration date has passed. If the expiration date has passed, return the entire pack to the pharmacy.**

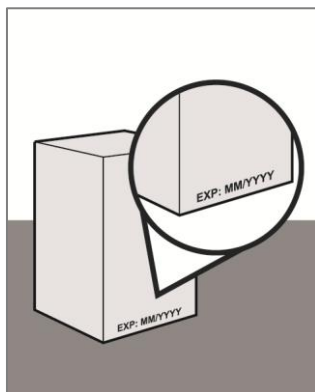


Figure B

3. **Wait 30 minutes.**
 - a. **Take the carton containing the STEQEYMA vial out of the refrigerator.**
 - b. **Leave the carton at room temperature 20 °C to 25 °C for 30 minutes to allow it to warm up (see Figure C).**
 - **Do not warm the vial using heat sources such as hot water or a microwave.**
 - **If the vial does not reach room**

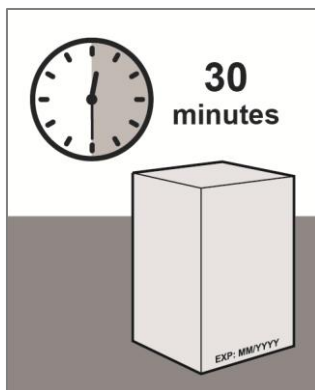


Figure C

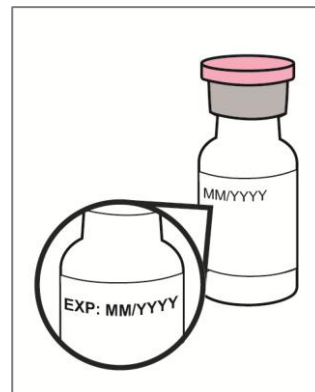


Figure D

- temperature, this could cause the injection to feel uncomfortable and make it hard to inject.
4. **Inspect the STEQEYMA vial.**
 - a. **Look at the vial and make sure you have the correct medicine (Steqeyma) and dosage.**
 - b. **Look at the vial and make sure it is not cracked or damaged.**
 - c. **Do not use STEQEYMA if the vial has been dropped or damaged.**
 - d. **Check the expiration date on the label of the vial (see Figure D).**
 - **Do not use STEQEYMA if the expiration date has passed.**

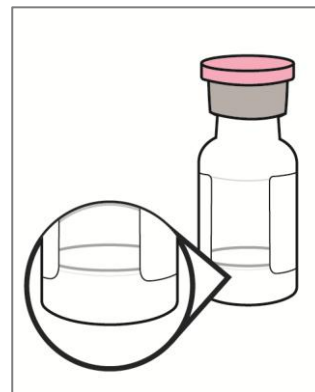


Figure E

5. **Inspect the medicine.**
 - a. **Look at the medicine in the vial and confirm that the liquid is clear to slightly opalescent and colourless to pale yellow. (see Figure E).**
 - **Do not use STEQEYMA if the liquid is discolored or cloudy, or if it contains visible flakes or particles.**

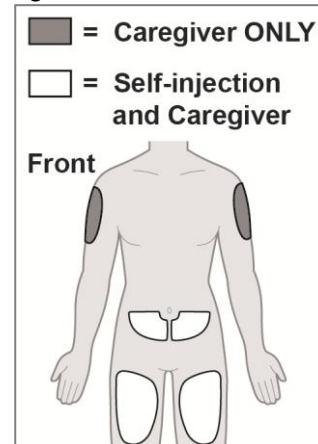


Figure F

6. **Choose an appropriate injection site (see Figure F).**
 - a. **You may inject into:**
 - the upper thighs.
 - the lower abdomen except for the 5 cm around the belly button.
 - the outer area of the upper arms 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 G**).

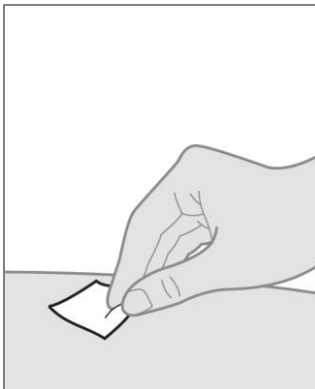


Figure H

8. **Clean the injection site.**

- a. Clean the skin with an alcohol swab where you plan to give your injection using a circular motion (see **Figure H**).
- Let your skin dry before injecting. Do not blow on or touch the injection site again before giving the injection.

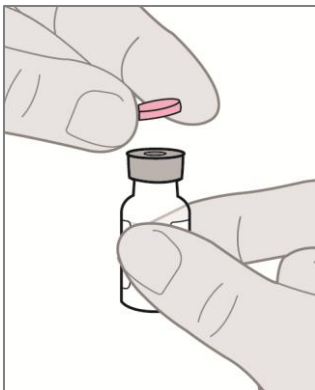


Figure I

9. **Remove the protective cap from the vial.**

- a. Remove the protective cap from the STEQEYMA vial (see **Figure I**).
- **Do not** remove the rubber stopper.



Figure J

10. **Clean the rubber stopper.**

- a. Wipe the rubber stopper of the vial with an alcohol swab and allow it to dry (see **Figure J**).
- **Do not** touch the rubber stopper after you have cleaned it.
- b. Place the vial on a flat surface.

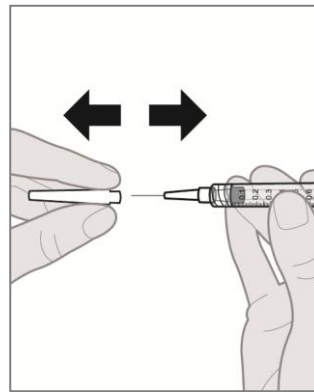


Figure K

11. **Remove the needle cap from the syringe.**

- a. Hold the syringe at the middle of the syringe body with the needle pointing away from yourself, and pull the needle cap straight off the syringe (see **Figure K**).
 - b. Dispose of the needle cap right away in a sharps disposal container (see **Step 19. Dispose of Steqeyma**).
- **Do not** re-cap the syringe.
 - **Do not** touch the needle or let the needle touch anything. Doing so may result in a needle stick injury.
 - **Do not** use the syringe if it has been dropped without the needle cap in place. If this happens call your doctor, nurse or health professional for further instructions.

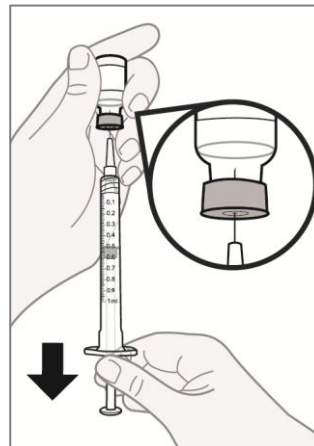


Figure L

12. **Withdraw the correct dose.**

- a. Put the vial on a flat surface and push the needle through the rubber stopper of the vial.
 - b. Leave the needle in the vial and turn both the syringe and vial upside down (vial on top).
 - c. Hold the syringe and vial firmly in one hand. Make sure the tip of the needle is in the liquid.
- It is important that the needle tip is always in the liquid. This stops air bubble from forming in the syringe.
- d. With your other hand, pull on the plunger rod to fill the syringe with the amount of liquid prescribed by your doctor (see **Figure L**).
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose.

For adults and paediatric patients (children and adolescents) 6 years of age and older, who weigh 60 kg

or more, pull on the syringe plunger to fill the syringe with the amount of liquid prescribed by your healthcare provider (0.5 mL or 1.0 mL).

For children and adolescents 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your healthcare provider may be less than 0.5 mL. Your healthcare provider will recommend how much liquid is needed.

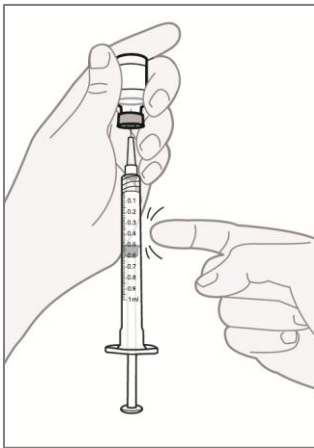


Figure M

13. **Check for air bubbles.**

- **Do not** remove the needle from the vial.
 - a. Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
 - b. If there are air bubbles, gently tap the side of the syringe until the air bubbles go to the top of the syringe (see **Figure M**).
 - c. Press the plunger rod until all of the air bubbles (but none of the liquid) have been removed.
- **Do not** lay the syringe down, or allow the needle to touch anything.

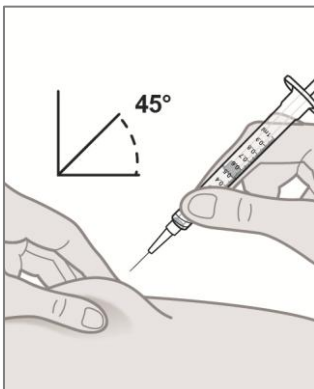


Figure N

14. **Insert the needle into the injection site.**

- a. Hold the body of the syringe in one hand between the thumb and index fingers (see **Figure N**).

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).

- b. With a quick and 'dart-like motion', insert the needle completely into the pinched skin at a

45-degree angle (see **Figure N**).

- **Do not** pull back on the plunger rod at any time.

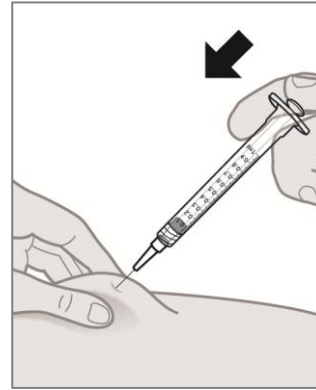


Figure O

15. **Give the injection.**

- c. After the needle is inserted use your thumb to slowly and evenly push the plunger rod all the way to the bottom of the syringe body. Keep the skin gently pinched.
- Make sure you have injected all of the STEQEYMA liquid (see **Figure O**).

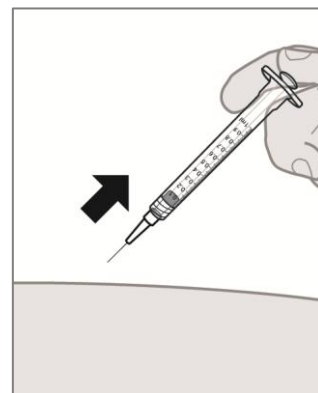


Figure P

16. **Remove the syringe from the injection site.**

- a. After the syringe is empty, release the pinched skin and slowly move the syringe away from the injection site (see **Figure P**).
- **Do not** re-cap the used needle. Recapping the used needle can lead to a needle-stick injury.
 - **Do not** reuse the syringe.
 - **Do not** rub the injection site.

17. **Care for the injection site.**

- Gently press an alcohol swab over the injection site for a few seconds after the injection. There may be a small amount of blood or liquid at the injection site. This is normal.

If some bleeding occurs, you can press a cotton ball or gauze over the injection site and hold for 10 seconds.

You may cover the injection site with a small adhesive bandage, if necessary.

18. **If your dose requires 2 injections, IMMEDIATELY give second injection.**

- If your dose is 90 mg, you will have two 45 mg vials. You will need to give yourself a second injection right after the first one.
 - a. **Repeat Steps 5-17 for the second injection using a new vial, needle and syringe.**
- Choose a different site for the second injection.



Figure Q

19. **Dispose of STEQEYMA.**
- Put the used syringe in a sharps container right away after use (see **Figure Q**).
- Do not** throw away (dispose of) the 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 re-used. 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.

How to inject STEQEYMA from a pre-filled syringe (45 mg or 90 mg)

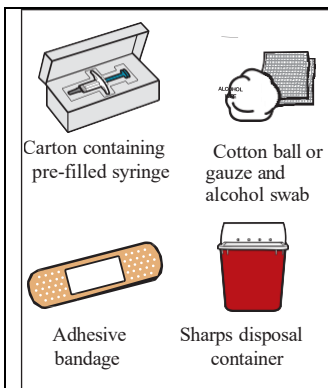


Figure A

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 A**)

Carton containing pre-filled syringe

Not included in the carton:

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

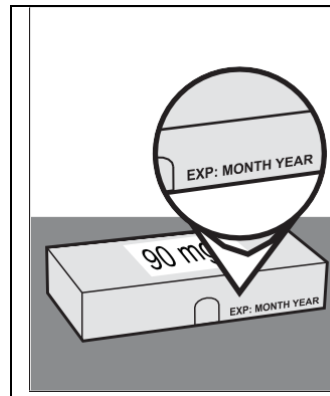


Figure B

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

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

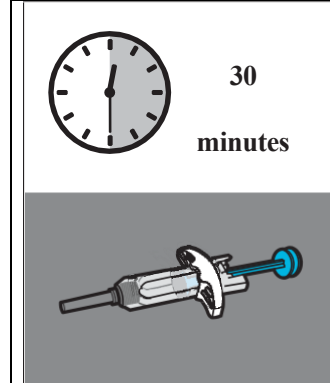


Figure C

3. Wait 30 minutes.

- 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 C**).

- 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.

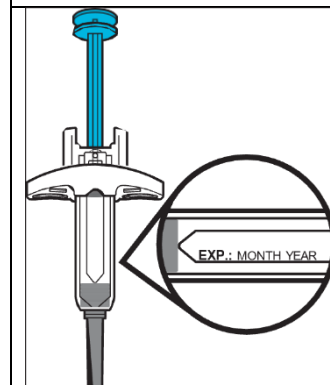


Figure D

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 45 mg you will get one 45 mg pre-filled syringe of STEQEYMA.
 - 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.

d. Check the expiration date on the label of the pre-filled syringe (see **Figure D**).

- **Do not** use if the expiration date has passed.
- **Do not** shake the pre-filled syringe.

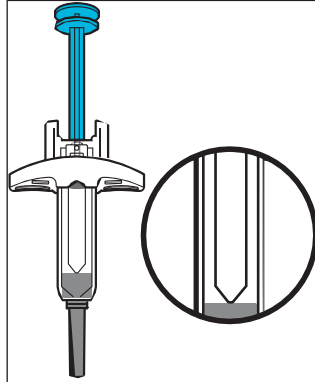


Figure E

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 E**).

- **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.

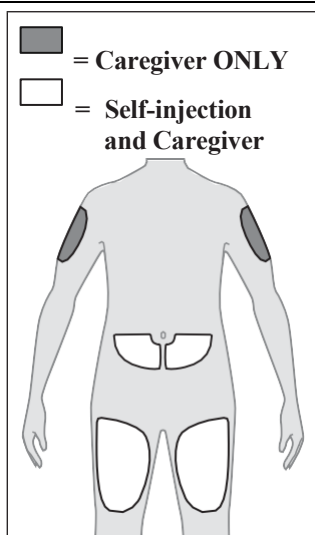


Figure F

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

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.

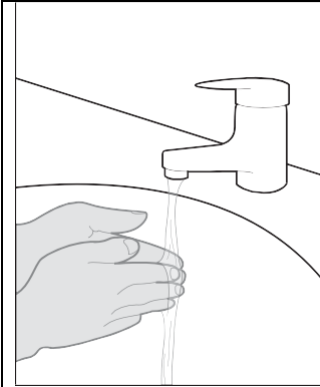


Figure G

7. Wash your hands.

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

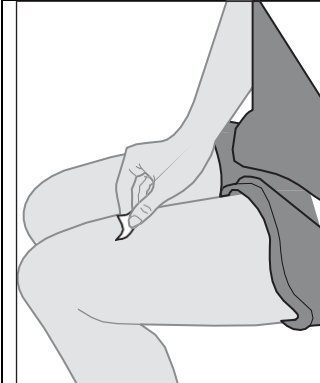


Figure H

8. Clean the injection site.

a. Clean the injection site with an alcohol swab using a circular motion (see **Figure H**).

b. Let the skin dry before injecting.

- **Do not** blow on or touch the injection site again before giving the injection.

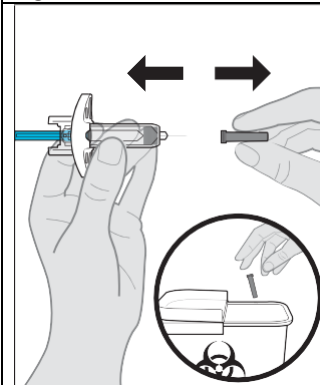


Figure I

9. Remove the cap.

a. 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 I**).

- **Do not** hold the plunger 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.

b. Dispose of the cap right away in a sharps disposal container (see **Step 14** and **Figure I**).

- **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.

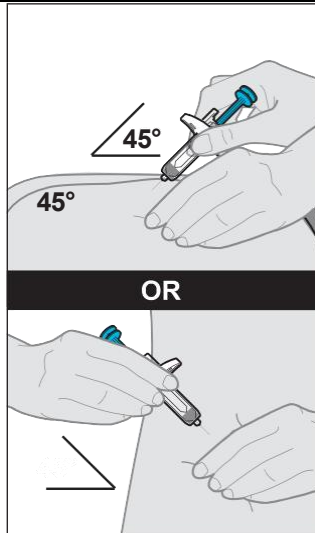


Figure J

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 J**).

- Do not** pull back on the plunger rod at any time.

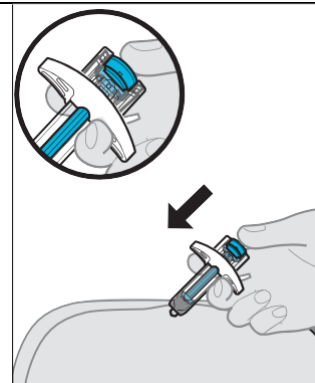


Figure K

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 K**).

- 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.

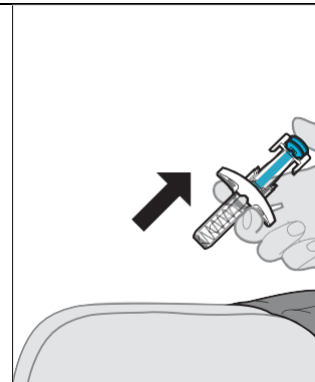


Figure L

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

- 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 L**).

- 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.

13. Care for the injection site.

- 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 M

14. Dispose of STEQEYMA.

- Put the used pre-filled syringe in a sharps disposal container right away after use (see **Figure M**).
- Do not throw away (dispose of) the pre-filled syringe in your household trash.

Dispose of sharps in an appropriate container according to your local regulations.

- 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.

How to inject STEQEYMA from a pre-filled pen (45 mg or 90 mg)

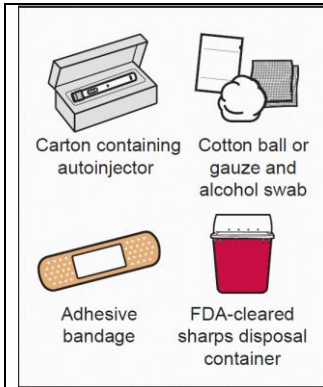


Figure A

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 1 carton containing the autoinjector from the refrigerator.
- Make sure you have the following supplies (see **Figure A**)
 - 1 Autoinjector

Not included in the carton:

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

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

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

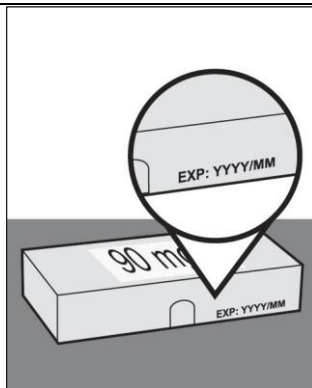


Figure B

3. Wait 30 minutes.

- Open the carton. And remove the autoinjector.
- Leave the autoinjector at room temperature 68°F to 77°F (20°C to 25°C) for about 30 minutes to allow it to warm up (see **Figure C**).
 - This will let the liquid come to a comfortable temperature for injection (room temperature).
 - **Do not** warm the autoinjector using heat sources such as hot water or a microwave.

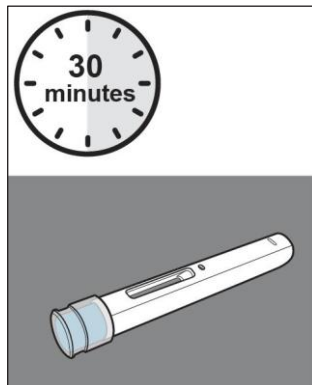


Figure C

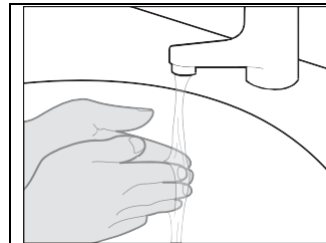


Figure D

4. Wash your hands.

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

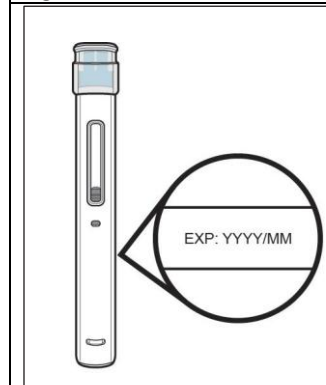


Figure E

5. Inspect the autoinjector.

- Look at the autoinjector and make sure you have the correct medicine (STEQEYMA) and dosage.
- Look at the autoinjector and make sure it is not cracked or damaged.
- Check the expiration date on the label of the autoinjector (see **Figure E**).
 - **Do not** shake the autoinjector.
 - **Do not** use the autoinjector if:
 - it has been dropped onto a hard surface.
 - it has been cracked or damaged.
 - the expiration date has passed.

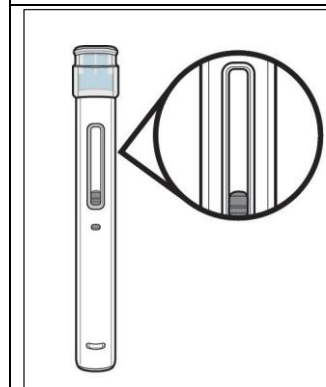


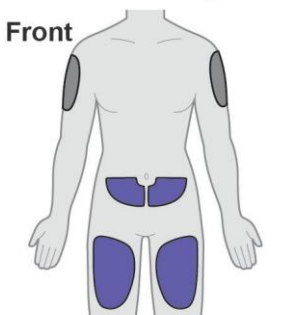
Figure F

6. Inspect the medicine.

- 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, cloudy, or has large particles
 - You may see air bubbles in the liquid. This is normal.

= Caregiver ONLY
 = Self-injection and Caregiver

Front



Back

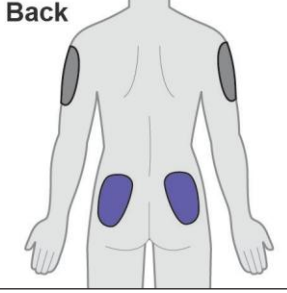


Figure G

7. Choose an appropriate injection site (see Figure G).

- You may inject into:
 - The front of your upper thighs.
 - The buttocks
 - your stomach (abdomen) except for the 2 inches (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.
- Choose a different injection site for each new injection at least 2.5 cm away from the area used for the last injection.

8. Clean the injection site.

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

9. Remove the cap.

- Hold the autoinjector in one hand by the injector body with the cap on top. Gently pull the cap straight off with the other hand (see **Figure I**).
 - 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.

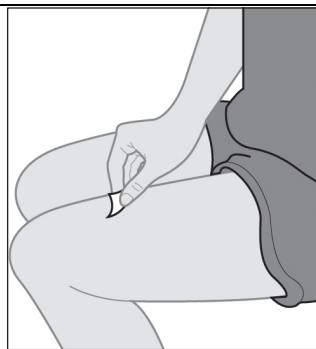


Figure H

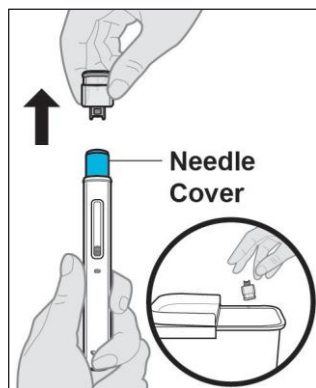
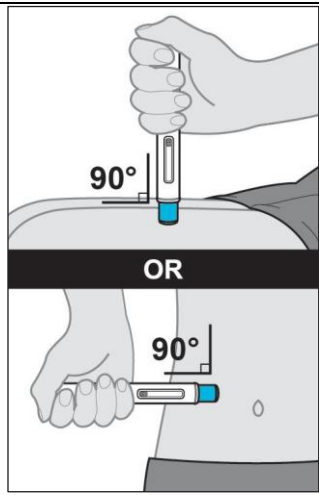


Figure I

10. Place the autoinjector on the injection site.

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


Figure J



11. Give the injection.

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

Figure K



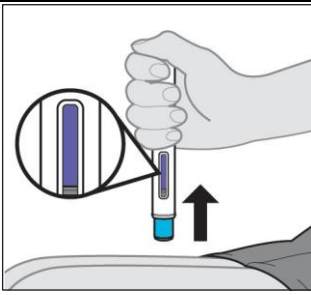


Figure L

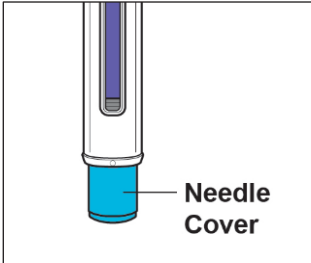


Figure M

12. Remove the autoinjector from the injection site.

- a. Look at the autoinjector and make sure that the light lilac plunger rod 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 lilac or if the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.
- b. Remove the autoinjector from your skin (see Figure L).
 - After you remove the autoinjector from the injection site, the needle will be automatically covered (see Figure M).
 - **Do not** reuse the autoinjector.
 - **Do not** rub the injection site.

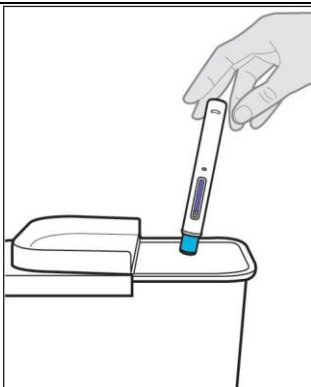


Figure N

13. Dispose of the autoinjector

- a. Throw away the used autoinjector in a sharps disposal container immediately after use (see Figure N).
- b. The alcohol swab and packaging may be put 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 labelled to warn of hazardous

waste inside the container. When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles and syringes.

- **Do not** dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

14. Care for the injection site Dispose of STEQEYMA.

- 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.

If you forget to use STEQEYMA

Make the next injection as soon as you remember, and then continue to use it as you would normally.

Do not take a double dose to make up for the dose you missed.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

If you use too much STEQEYMA

If you think that you have used too much STEQEYMA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using STEQEYMA?

Things you should do

- Always follow your doctor's instructions carefully.
- Tell your doctor about your medical conditions before each treatment (see Before you use STEQEYMA).
- Tell your doctor if you become pregnant while using STEQEYMA.
- If you used STEQEYMA while pregnant, tell your baby's doctor about your STEQEYMA use before the baby receives any vaccines, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine or any other live vaccines.
- If you develop headache, vision problems, seizures or change in mental status (for example confusion), tell your doctor immediately.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using STEQEYMA.

Call your doctor straight away if you:

- get symptoms of an infection, such as a fever, skin sores or feeling tired
- become pregnant while using STEQEYMA. Remind any doctor, dentist or pharmacist you visit that you are using STEQEYMA.

Things you should not do

- Do not stop using this medicine suddenly without checking with your doctor
- You should not receive a live vaccine while taking STEQEYMA.
- Do not use STEQEYMA to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how STEQEYMA affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information on the effects of taking STEQEYMA with alcohol

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store all presentations of STEQEYMA between 2°C and 8°C in the refrigerator. Do not freeze.

Keep the products in the original cartons to protect from light until the time of use. Do not shake.

STEQEYMA pre-filled syringes and pre-filled pen - room temperature storage:

If needed, you may store STEQEYMA pre-filled syringes and pre-filled pens at room temperature up to 25°C for one period of up to 31 days within the shelf-life. Once the pre-filled syringes and pre-filled pens have been stored at

room temperature, they should not be returned to the refrigerator. Discard the pre-filled syringe or pre-filled pen if not used within 31 days at room temperature storage.

- Write the date on the carton, when removed from the refrigerator.

STEQEYMA 45 mg/0.5 mL vial (for subcutaneous use) – room temperature storage:

If needed, you may store STEQEYMA 45 mg/0.5 mL vial at room temperature up to 30°C for one period of up to 15 days.

- Write the date on the carton, when removed from the refrigerator
- Once 45 mg/0.5 mL vial has been stored at room temperature, do not put it back in the refrigerator
- Throw away 45 mg/0.5 mL vial if it has been kept for 15 days and has not been used or reached its original expiry

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

For pre-filled pen only, before use, remove the carton from the refrigerator and keep the pre-filled pen inside the carton and allow to reach room temperature by waiting for 30 minutes.

Keep it where young children cannot reach it.

Heat and dampness can destroy some medicines.

When to discard your medicine

- After injection, used syringes and pens should be placed in a puncture-resistant container, like a sharps container.
- Empty vials, antiseptic wipes, and other supplies can be placed in regular rubbish.
- Dispose of your sharps container according to your state or local regulations.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Injection site or Infusion-related reactions:</p> <ul style="list-style-type: none"> fever or chills bruising bleeding pain swelling redness itching or hives chest pain low or high blood pressure <p>Lungs and upper airways:</p> <ul style="list-style-type: none"> cold sore throat runny nose blocked or stuffy nose cough sinus infection <p>Skin and nail:</p> <ul style="list-style-type: none"> rash eczema itching cellulitis acne yellow or white skin blisters peeling of skin <p>Ears, eyes and mouth:</p> <ul style="list-style-type: none"> blisters or sores in mouth dental infections <p>Brain and nerves:</p> <ul style="list-style-type: none"> headache dizziness <p>Gut and digestion:</p> <ul style="list-style-type: none"> diarrhoea nausea vomiting <p>Musculoskeletal:</p> <ul style="list-style-type: none"> back pain muscle aches joint pain <p>Body as a whole:</p> <ul style="list-style-type: none"> fever fatigue infections feeling weak 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Signs of an allergic reaction, such as:</p> <ul style="list-style-type: none"> chest tightness, shortness of breath, wheezing or difficulty breathing, 	<p>Call your doctor straight away, or go straight to the</p>

<ul style="list-style-type: none"> swelling of the face lips, tongue or other parts of the body, hives itching or skin rash Serious infections Cancer 	<p>Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Tell your doctor if you notice any other side effects, particularly if they bother you or do not go away. In general, the side effects of STEQEYMA in children and adolescents 6 years and older are similar to those in adults. Ask your doctor or pharmacist for more information.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What STEQEYMA contains

<p>Active ingredient (main ingredient)</p>	<p>45 mg vial or 45 mg, 90 mg pre-filled syringe or pre-filled pen 45 mg ustekinumab 90 mg ustekinumab 130 mg vial 130 mg Ustekinumab</p>
<p>Other ingredients (inactive ingredients)</p>	<p>45 mg vial or 45 mg, 90 mg pre-filled syringe or pre-filled pen</p> <ul style="list-style-type: none"> - Histidine - Histidine monohydrochloride monohydrate - Sucrose - Polysorbate 80 - Water for injections <p>130 mg vial</p> <ul style="list-style-type: none"> - Histidine - Histidine monohydrochloride monohydrate - Methionine - Disodium edetate - Sucrose - Polysorbate 80

	- Water for injections
--	------------------------

Do not take this medicine if you are allergic to any of these ingredients.

What STEQEYMA looks like

STEQEYMA injection for subcutaneous use is clear to slightly opalescent, colourless to pale yellow solution and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions containing protein.

STEQEYMA solution for intravenous use is clear to slightly opalescent, colourless to pale yellow product.

STEQEYMA is available in pack sizes of 1 in the following presentations.

For subcutaneous use:

45 mg ustekinumab in 0.5 mL concentrate solution in a glass vial (AUST R 475406).

45 mg ustekinumab in 0.5 mL solution in a pre-filled syringe (AUST R 420572).

90 mg ustekinumab in 1.0 mL solution in a pre-filled syringe (AUST R 420570).

45 mg ustekinumab in 0.5 mL solution in a pre-filled pen (AUST R 500306).

90 mg ustekinumab in 1.0 mL solution in a pre-filled pen (AUST R 500305).

For intravenous infusion only:

130 mg ustekinumab in 26 mL concentrate solution in a glass vial (AUST R 420571).

Who distributes STEQEYMA

Celltrion Healthcare Australia Pty Ltd.

Suite 13-03 31 Market Street,
Sydney NSW 2000, Australia

Phone: 1800 325 228

This leaflet was prepared in December 2025.