

Steqeyma[®]

Ustekinumab 45mg/0.5mL Solution for Injection in Pre-filled Syringe
 Ustekinumab 90mg/1.0mL Solution for Injection in Pre-filled Syringe

What is in this leaflet

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What Steqeyma[®] is used for

Steqeyma is a prescription medicine that is approved for the treatment of:

- Adults 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
- Adults with moderately to severely active Crohn's disease or ulcerative colitis

How Steqeyma[®] works

Steqeyma 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 or Crohn's disease, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body. Steqeyma can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

Before you use Steqeyma[®]

- *When you must not use it*

You should not receive Steqeyma if you have:

- had an allergic reaction to Steqeyma, or any of the other ingredients in Steqeyma. See the end of this labeling for a complete list of ingredients in

Steqeyma.

- *Before you start to use it*

Your doctor will assess your health before each treatment.

Tell your doctor about all of your medical conditions before each treatment, including if you:

- ever had an allergic reaction to Steqeyma. Ask your doctor if you are not sure.
- 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.
- have recently received or are scheduled to receive a vaccine. Tell your doctor if anyone in your household needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.
- are receiving or have received 'allergy shots', especially for serious allergic reactions.
- are pregnant, planning to become pregnant, or breastfeeding. Ask your doctor for advice before taking this medicine. Steqeyma should be used during a pregnancy if needed. Steqeyma may pass into your breast milk in very small amounts. Women who are breastfeeding should talk to their doctor about whether to use Steqeyma
- have an allergy to latex.

- *Pregnancy and lactation*

Please consult your doctor or

pharmacist if you are pregnant, planning for pregnancy or breastfeeding before using Steqeyma

- *Taking other medicines*

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

How to use Steqeyma[®]

- For treatment of psoriasis and psoriatic arthritis, Steqeyma is given by injection under the skin.
- For treatment of Crohn's disease or ulcerative colitis, the first dose of Steqeyma is given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. This dose is given by your healthcare provider. After that, Steqeyma is given by injection under the skin.
- Steqeyma is intended for use under the guidance and supervision of your doctor. If your doctor determines that it is appropriate, you may be able to administer Steqeyma under the skin to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "**Instructions for Injecting Steqeyma under the skin yourself**").
- Your doctor will determine the right dose of Steqeyma for you, the amount for each injection 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

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scheduled follow-up
 appointments.

Instructions for Injecting Steqeyma under the skin yourself

Your first Steqeyma may be administered by your 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. **Before you self-inject Steqeyma, you must be trained by a healthcare professional. 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 should not be used:

- after the expiry date on the label;
- if the seal is broken;
- if the liquid is discolored, cloudy or you can see other particulate matter floating in it;
- if you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

Always keep medicine out of the reach of children.

To reduce the risk of accidental needle sticks to users, each pre-filled syringe is equipped with a needle guard that is automatically activated to cover the needle after complete delivery of the syringe content.

Do not shake Steqeyma at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

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

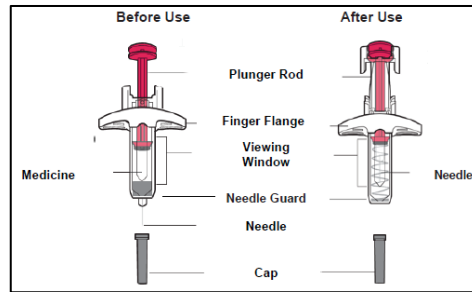


Figure A

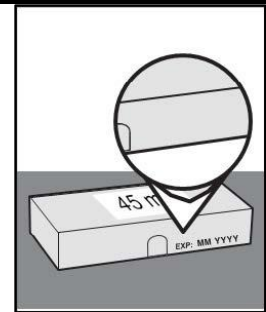


Figure C

Preparing for the injection:

1. Gather the supplies for the injection

- Prepare a clean, flat surface, such as a table or countertop, 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

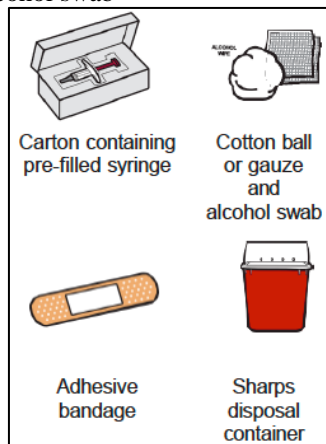


Figure B

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.

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.

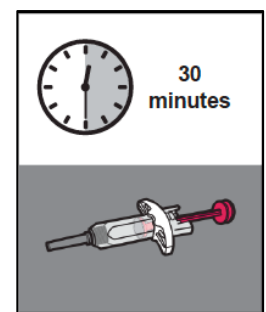


Figure D

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:

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- 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 two 45 mg pre-filled syringes 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. Or you will get one 90 mg pre-filled syringe of Steqeyma.
- c) 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 E).
- **Do not** use if the expiration date has passed.
 - **Do not** shake the pre-filled syringe.

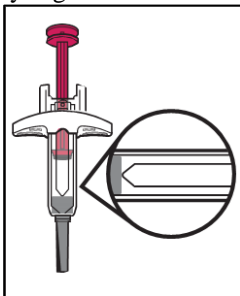


Figure E

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 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.

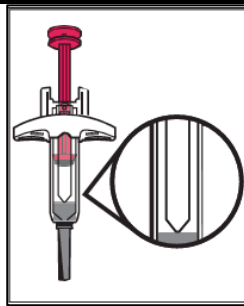


Figure F

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.

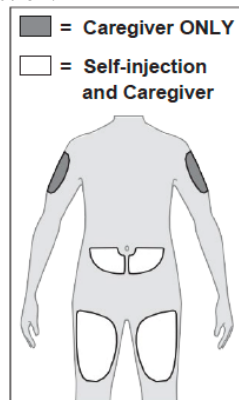


Figure G

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.

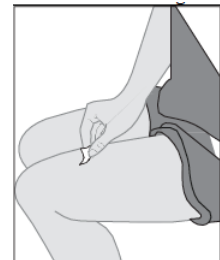


Figure I

Administering the Injection:

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 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 the needle. This is normal.
- b) Dispose of the cap right away in a sharps disposal container (see Figure J).
- **Do not** use the pre-filled syringe if it is dropped without the needle cover in place. If this happens,

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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.

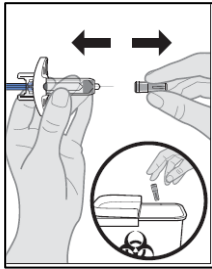


Figure J

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 K*).

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

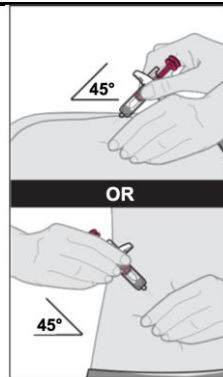


Figure K

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 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 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 M*).
 - If the Needle is not covered, proceed carefully to dispose of the syringe.

- **Do not** reuse the pre-filled syringe.
- **Do not** rub the injection site.

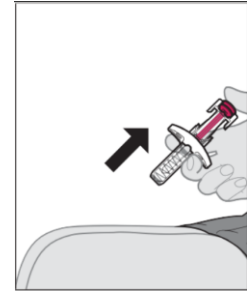


Figure M

After the injection:

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.

14. Dispose of Steqeyma

- Put the used pre-filled syringe in a sharps disposal container right away after use (*see Figure N*).
- 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 not 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

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use. These measures will help protect the environment.



Figure N

- How much to use

Your doctor will determine the right dose of Steqeyma for you, the amount for each injection 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.

- When to use it

Use as directed by your doctor or pharmacist

- How long to use it

Continue taking Steqeyma for as long as your doctor recommends.

- If you forget to use it

Make the next injection as soon as you remember. Do not double up the injections.

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 (overdose)

Immediately telephone your doctor, or go to Accident and Emergency at your nearest hospital

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must 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 are about to start taking a new medicine, tell your doctor and pharmacist that you are using Steqeyma.

- Things you must not do

- You should not receive a live vaccine while taking Steqeyma.
- If you used Steqeyma while pregnant, tell your baby's doctor about your Steqeyma use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.
- Medicines are sometimes prescribed for purposes that are not mentioned in patient information sheets. Do not use Steqeyma for a condition for which it was not prescribed.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

- Things to be careful of

Driving and using machines

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

Side effects

Steqeyma is a medicine that may decrease the activity of your immune system. It can increase your chances of getting serious side effects including:

Serious Infections

- Steqeyma may lower your ability to fight infections. Some infections could become serious and lead to

hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using Steqeyma. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.

- Your doctor will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with Steqeyma and during treatment with Steqeyma.

Cancer

- Many drugs such as Steqeyma that may decrease the activity of the immune system may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

Other serious side effects may occur including allergic reactions.

Signs of a serious allergic reaction may include a skin rash, a swollen face, lips, mouth or throat or wheezing, dizziness, trouble swallowing or breathing. Tell your doctor or get emergency medical help right away if you think you are having an allergic reaction.

In rare cases, symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction to Steqeyma.

Allergy to latex

The needle cover on the pre-filled syringe contain dry natural rubber (a

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form of latex). This may cause allergic reactions in people who are sensitive to latex. Tell your doctor if you have ever had an allergic reaction to latex and developed any allergic reaction to Steqeyma injection.

The most common side effects of Steqeyma are:

- Upper respiratory infections such as common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

These are not all the side effects with Steqeyma. Tell your doctor about any side effect that bothers you or does not go away. Ask your doctor or pharmacist for more information.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers → Reporting side effects to medicines (ConSERF) or vaccines (AEFI)].

Storage and Disposal of Steqeyma[®]

- Storage

If you are using Steqeyma at home, it is important to store the product in your refrigerator although not in the freezer compartment. Steqeyma should not be frozen. Keep the product in the original carton to protect from light until the time of use.

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 30 days in the original carton with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the space provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

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

Product Description

What it looks like

- Pre-filled syringe
 Steqeyma is a colourless to light yellow product and may contain a few small translucent or white particles of protein. This appearance is not unusual for solutions containing protein.

Steqeyma 45mg/0.5ml solution for injection in pre-filled syringe

- Packs of:
- 1 pre-filled syringe

Steqeyma 90mg/1.0ml solution for injection in pre-filled syringe

- Packs of:
- 1 pre-filled syringe

Ingredients

- Active ingredient
 The active ingredient is Ustekinumab.
- Inactive ingredients
 The inactive ingredients include: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injections

- MAL number

MALXXXXXXXX

Manufacturer

CELLTRION Pharma, Inc.
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Batch Releaser

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Product Registration Holder

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