

INSTRUCTION FOR USE

Uzpruvo® 45 mg solution for injection in pre-filled syringe ustekinumab for subcutaneous use

Read carefully these instructions for use before using Uzpruvo® solution for injection in pre-filled syringe.

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 Uzpruvo® yourself. If this happens, you will get training on how to inject Uzpruvo®. Talk to your doctor if you have any questions about giving yourself an injection.

Important information you need to know before injecting Uzpruvo® solution for injection in pre-filled syringe

Uzpruvo® solution for injection in pre-filled syringe is not suitable for intravenous use, other ustekinumab products must be used for the initiation of treatment of Crohn's disease.

Uzpruvo® solution for injection in pre-filled syringe is not suitable for paediatric patients below 60 kg of body weight, other ustekinumab products allowing weight-based dosing must be used.

Important information:

- For subcutaneous use only
- Do not mix Uzpruvo® with other liquids for injection
- Do not shake Uzpruvo® pre-filled syringes. This is because shaking may damage the medicine. Do not use the medicine if it has been shaken. Get a new pre-filled syringe.

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 Uzpruvo®
 - If your dose is 90 mg you will get two 45 mg pre-filled syringes of Uzpruvo® 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
- it is the right medicine
- it has not passed its expiry date
- the pre-filled syringe is not damaged
- the solution in the pre-filled syringe is clear and colourless to slightly yellow and practically free of visible particles
- the solution in the pre-filled syringe is not frozen
- It should be allowed to reach room temperature (approximately half an hour).

Figure 1 shows what the Uzpruvo® pre-filled syringe looks like

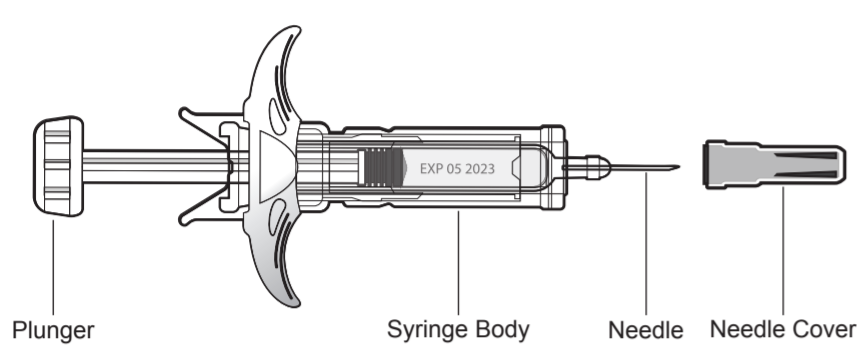


Figure 1

1. Prepare the materials

Gather the supplies you will need to prepare and to give your injection. You will need:

- Antiseptic wipes
- Cotton balls or gauze pads
- Adhesive bandage
- Your prescribed dose of Uzpruvo® (see Figure 1)
- Puncture-resistant sharps disposal container (not included). See Figure 2

Get everything together that you need and lay out on a clean surface.

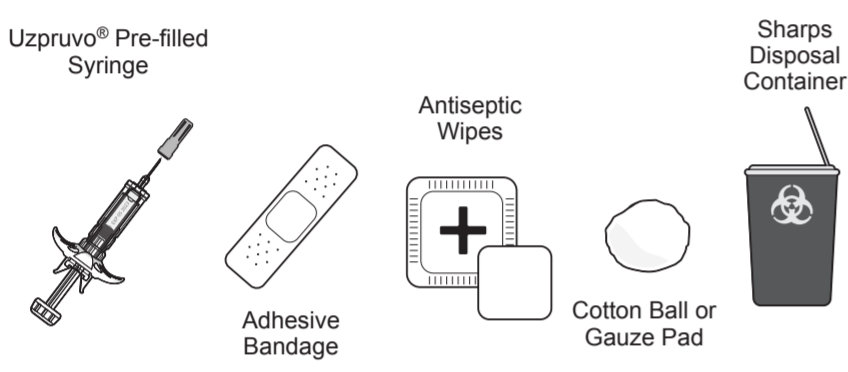


Figure 2

2. Choose and prepare the injection site:

Choose an injection site (see Figure 3)

- Uzpruvo® is given by injection under the skin (subcutaneously)
- Choose an injection site. Good places for the injection are the upper thigh (legs), buttocks, or around the belly (abdomen) at least 5 cm away from the navel (belly button)
- If a caregiver is giving you the injection, the outer area of the upper arms may also be used (see Figure 3)
- Use a different injection site for each injection. Do not give an injection in an area of the skin that is tender, bruised, red or hard

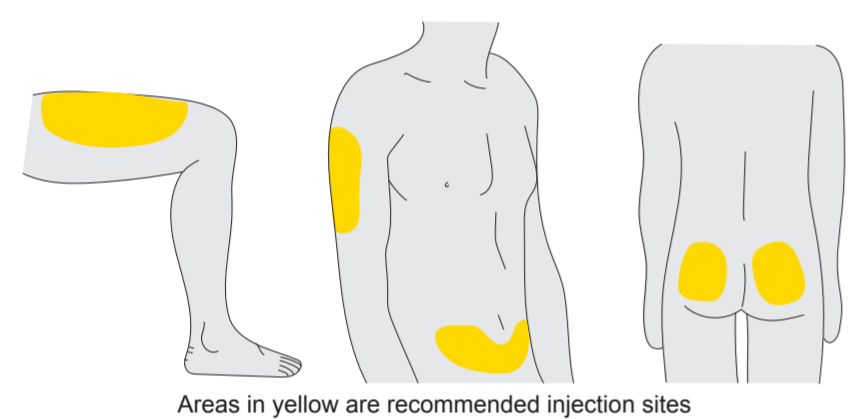


Figure 3

Prepare the injection site

- Wash your hands very well with soap and warm water
- Clean the skin with the antiseptic wipe where you plan to give your injection
- Do not touch this area again before giving the injection. Let your skin dry before injection
- Do not fan or blow on the clean area
- Do not inject through clothes

3. Remove the needle cover (see Figure 4):

- Remove the needle cover when you are ready to inject Uzpruvo®
- Do not touch the plunger while removing the needle cover
- Hold the body of the pre-filled syringe with one hand, and pull the needle cover straight off (see Figure 4)
- Put the needle cover in the trash. Do not recap
- You may also see a drop of liquid at the end of the needle. This is normal
- Do not touch the needle or let it touch anything
- Inject the dose promptly after removing the needle cover

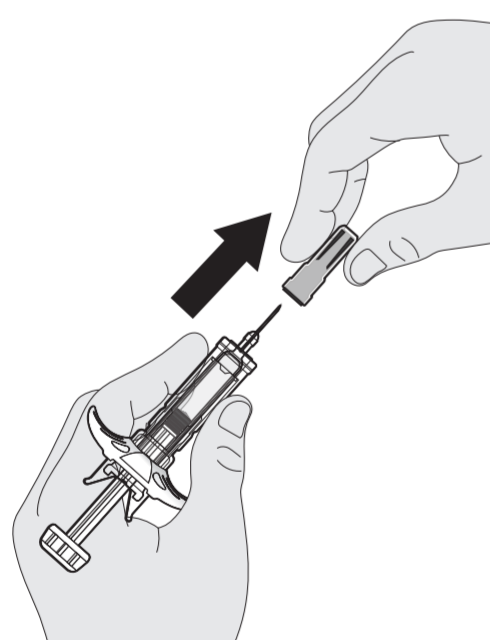


Figure 4

4. Inject the dose:

Grasp the syringe:

- Hold the body of the pre-filled syringe with one hand between the thumb and index finger (see Figure 5)
- 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 for instructions
- Do not pull back on the plunger at any time

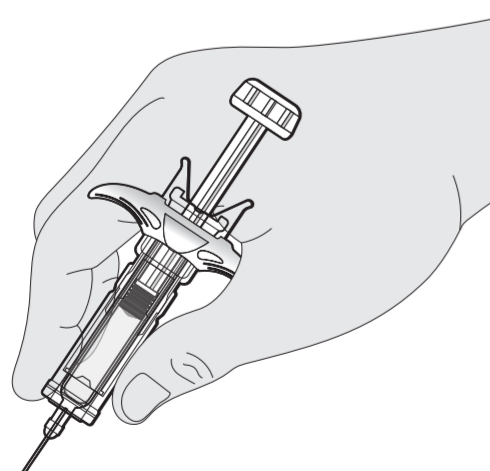


Figure 5

Pinch the skin and insert needle:

- Use the other hand to gently pinch the cleaned area of the skin. Hold firmly
- Use a quick, dart-like motion to insert the needle into the pinched skin at about 45-degree angle (see Figure 6)

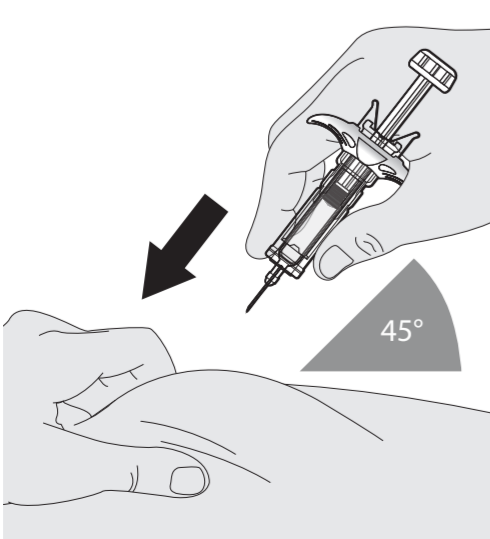


Figure 6

Inject the drug:

- Inject all of the liquid by using your thumb to push in the plunger all the way in until the pre-filled syringe is empty (see Figure 7)

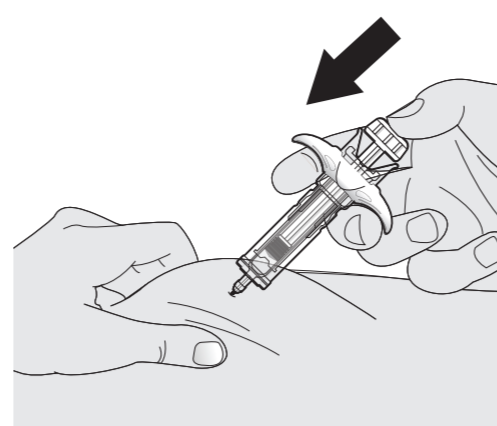


Figure 7

Allow the needle to retract:

- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin
- Slowly take your thumb off the plunger head. The plunger will move up with your finger and retract the needle into the needle guard (see Figure 8)

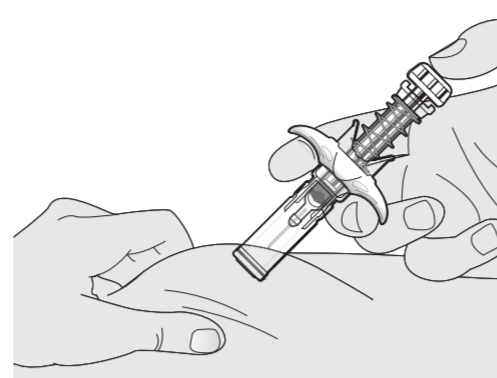


Figure 8

5. After the injection:

- After completing the injection, press a cotton ball or gauze pad on the skin of the injection site for a few seconds after the injection (see Figure 9)
- There may be a slight bleeding at the injection site. This is normal
- Do not rub the skin at the injection site
- You may cover the injection site with a small adhesive bandage, if necessary

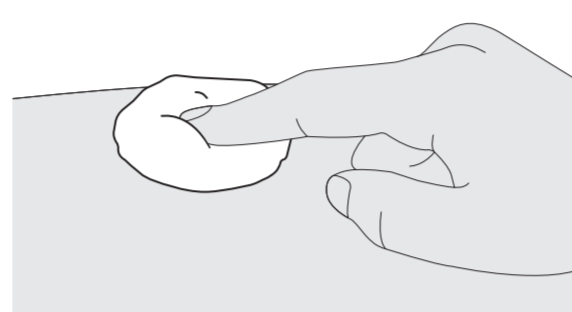


Figure 9

6. Disposal:

- Put the used syringes in a puncture-resistant container, like a sharps disposal container right away after use according to your local regulations. Do not throw away (dispose of) loose syringes in your household garbage (see Figure 10)
- Dispose of the antiseptic wipes, cotton ball or gauze pad, and packaging in your garbage
- Never re-use a syringe, for your safety and health, and for the safety of others

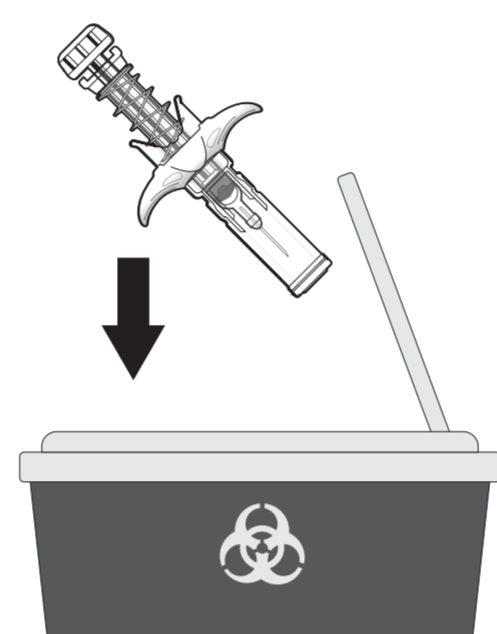


Figure 10