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| <div>▼ 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.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           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| <div><b>Read all of this leaflet carefully before you start using this medicine because it contains important information for you.</b></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           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## Instructions for use

### Otulf 90 mg solution for injection in pre-filled pen

ustekinumab

This "Instructions for Use" contains information on how to inject OTULFI using the 90 mg/1 mL single dose pre-filled pen (OTULFI pre-filled pen).

Read and follow the Instructions for Use that come with your OTULFI pre-filled pen before you start using it and each time you get a refill. There may be new information. This information does not replace talking to your doctor or pharmacist about your medical condition or treatment.

If you have any questions about using your OTULFI pre-filled pen, please call your doctor or pharmacist.

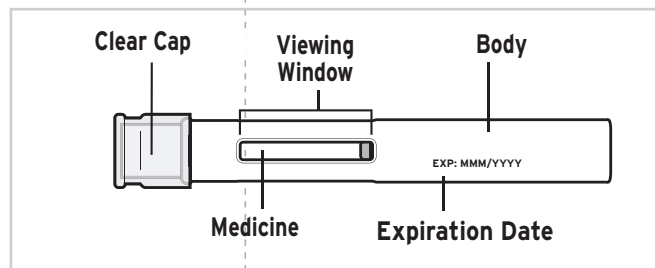
#### Important information you need to know before injecting OTULFI

- Read the package leaflet that comes with your OTULFI pre-filled pen for important information you need to know before using it.
- For subcutaneous injection only** (inject directly under the skin).
- If your doctor decides that you or a caregiver can give your OTULFI injection at home, you should receive training on the right way to prepare and inject OTULFI. Do not try to inject OTULFI yourself until you have been shown the right way to give the injections by your doctor or nurse.
- Do not** reuse the OTULFI pre-filled pen. The OTULFI pre-filled pen is for single-dose (one-time) use only.
- Do not** share your OTULFI pre-filled pen with another person. You may give another person an infection or get an infection from them.
- Do not** remove the clear cap from the OTULFI pre-filled pen until you are ready to inject OTULFI.
- Do not** use the OTULFI pre-filled pen if it shows any signs of damage or if it has been dropped.
- Do not** try to take apart the OTULFI pre-filled pen at any time.

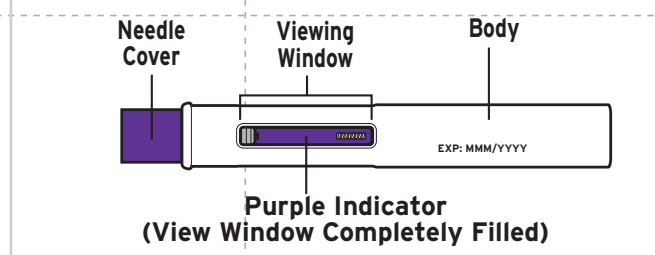
#### Storing OTULFI pre-filled pens

- Store OTULFI pre-filled pens in the refrigerator between 2°C to 8°C.
- Store unused OTULFI pre-filled pens in the original carton to protect from light.
- Do not** freeze OTULFI pre-filled pen. Do not use OTULFI pre-filled pen if it was frozen.
- Do not** expose OTULFI pre-filled pen to heat or direct sunlight.
- Do not** shake OTULFI pre-filled pen.
  - Prolonged vigorous shaking may damage the medicine.
  - Do not** use the OTULFI pre-filled pen if it has been shaken.
- OTULFI pre-filled pen may be stored at room temperature up to 30°C in the original carton for up to 30 days.
  - Do not** use OTULFI pre-filled pen if it has been out of the refrigerator for more than 30 days.
  - At any time before the end of this period, OTULFI pre-filled pen can be put back in the refrigerator once and kept there until the expiry date. Discard the pre-filled pen if not used after the maximum period of 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- When traveling on an airplane, always store OTULFI pre-filled pen in your carry-on luggage because the airplane luggage area can be very cold and OTULFI could freeze.

### Your OTULFI pre-filled pen Before Use

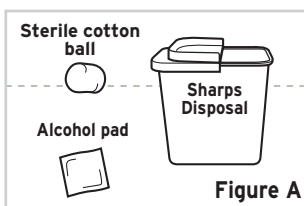


### After Use



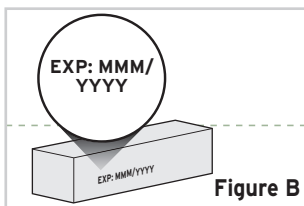
## Step 1 Preparing for your injection

- Choose a clean, flat surface, such as a table or countertop, in a well-lit area.
- Gather the following supplies (not included) (see **Figure A**):
  - a sterile cotton ball or gauze
  - an alcohol pad
  - a sharps disposal container (see **Step 8**)



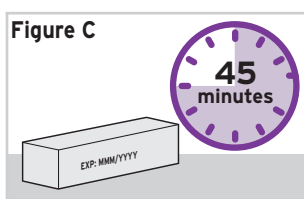
- Remove the carton containing the OTULFI pre-filled pen from the refrigerator.

- Check the carton to make sure that it is the medicine and dose that you are prescribed.
- Check the expiration date (EXP) on the carton to make sure the date has not passed (see **Figure B**).
- Check the carton for any signs of damage.



**Do not** use the OTULFI pre-filled pen if it looks like the carton has been opened.

- Let the carton sit on the chosen surface for 45 minutes before use to allow the medicine in the OTULFI pre-filled pen to reach room temperature (see **Figure C**).



**Do not** warm OTULFI pre-filled pen in any other way, such as in a microwave, hot water, or direct sunlight.

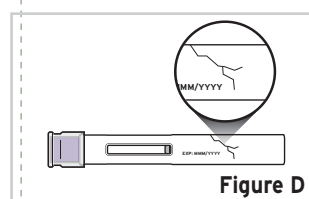
- Remove the OTULFI pre-filled pen from carton.

**Do not** remove the clear cap from the OTULFI pre-filled pen until you are ready to inject to avoid injury.

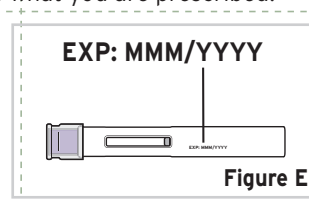
## Step 2 Check your OTULFI pre-filled pen

- Check the OTULFI pre-filled pen to make sure it is not cracked or damaged (see **Figure D**).

**Do not** use if the OTULFI pre-filled pen shows signs of damage or if it has been dropped.
- Check the OTULFI pre-filled pen label to make sure that:
  - The name on the pre-filled pen says OTULFI
  - The dose on the OTULFI pre-filled pen is what you are prescribed.
  - The expiration date (EXP) on the OTULFI pre-filled pen has not passed (see **Figure E**).



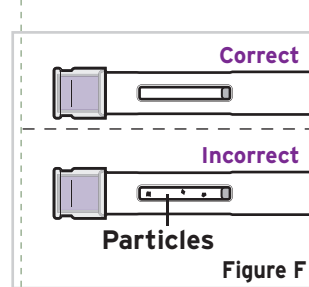
**Do not** use the pre-filled pen if the name on the label is not OTULFI, the dose is not what you are prescribed, or the expiration date on the label has passed.



- Look at the medicine in the viewing window. Make sure it is clear and colourless to slightly brown-yellow and does not contain any particles (see **Figure F**).

**Note:** Air bubbles in the medicine are normal.

**Do not** inject OTULFI if the medicine is frozen, cloudy, discoloured, or has lumps or particles in it because it may not be safe to use. Call your doctor or pharmacist for instructions.



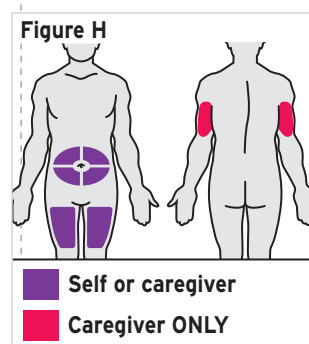
## Step 3 Wash your hands

- Wash your hands well with soap and water, then dry them with a clean towel (see **Figure G**).



## Step 4 Choose the injection site

- If you are giving yourself the injection, you can use:
  - The front of your upper thigh.
  - The belly (abdomen), except within 5 cm around the belly button (navel).
- If a caregiver is giving the injection, they can also use the outer area of the upper arm (see **Figure H**).



**Note:** Rotate to a different injection site (such as other leg, other side of the belly, etc.) for every injection.

**Do not** inject into skin that is sore (tender), bruised, red, or hard.

**Do not** inject through clothing.

## Step 5 Clean the injection site

- Wipe the skin where you want to inject with an alcohol pad to clean it (see **Figure I**). Let the skin dry.

**Do not** blow on or touch the site after cleaning.



## Step 6 Give your injection

When you are ready to inject, position the OTULFI pre-filled pen in your hand so you can clearly see the viewing window

Using your other hand, firmly pull the clear cap straight off without twisting (see **Figure J**).

**Note:** A few drops of medicine may come out of the needle, this is normal.

**Note:** Use the OTULFI pre-filled pen within 3 minutes after removing the clear cap to avoid contamination.

**Do not** try to put the clear cap back on the OTULFI pre-filled pen at any time, even at the end of the injection.

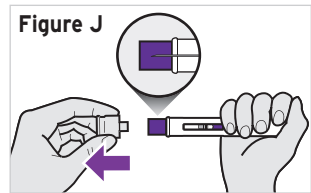
**Do not** touch the needle cover (the purple-coloured part located at the tip of the OTULFI pre-filled pen) because this might cause an accidental needle stick.

- Throw away the clear cap in a sharps disposal container (see **Step 8**).

**Read all of the remaining instructions in Step 6 before you start injecting to make sure you give the full dose.**

- Place the purple needle cover of the OTULFI pre-filled pen straight against your skin at a 90-degree angle. Make sure that you can see the viewing window (see **Figure K**).

**Note:** To make sure you inject under the skin (into the fatty tissue) do not tilt the OTULFI pre-filled pen.

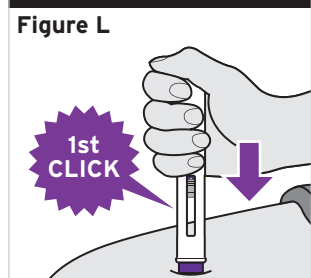


- In a single motion, push and hold the OTULFI pre-filled pen firmly against your skin until you hear a first click. This means the injection has started (see **Figure L**).
- Continue pushing the OTULFI pre-filled pen down on the injection site and listen for a second click which means that the injection is almost complete. This may take between 5 to 30 seconds (see **Figure M**).

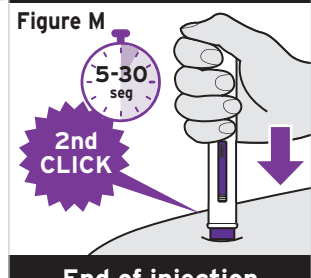
- Do not** lift the OTULFI pre-filled pen from the skin when you hear the second click because the medicine may not be fully injected.

- After you hear the second click, continue holding the OTULFI pre-filled pen in place and slowly count to 5 (see **Figure N**).

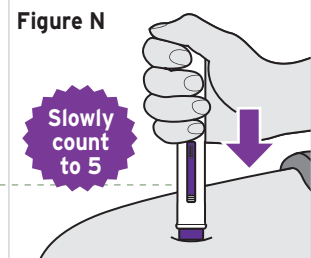
### Start of injection



### Injection is ongoing

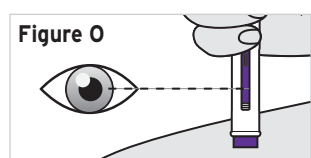


### End of injection



- While holding the OTULFI pre-filled pen in place, check to make sure the purple indicator has fully appeared in the viewing window and has stopped moving (see **Figure O**).

**Do not** try to repeat the injection with a new OTULFI pre-filled pen if the purple indicator did not come all the way down during the injection or you believe you did not get a full injection. Call your doctor or pharmacist if this happens.



## Step 7 Remove the OTULFI pre-filled pen from your skin

- When the injection is complete, lift the OTULFI pre-filled pen straight away from your skin (see **Figure P**).

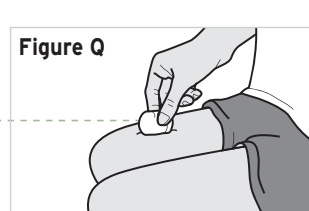
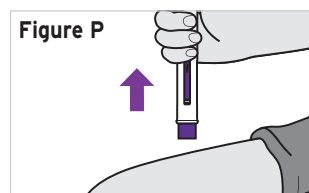
**Note:** The purple needle cover will slide down and cover the needle.

**Do not** put the clear cap back on the OTULFI pre-filled pen.

- If you see blood on the injection site, press gauze or a cotton ball on the skin until the bleeding stops (see **Figure Q**).

**Do not** rub the injection site.

- Throw away your used OTULFI pre-filled pen as described in **Step 8** and **Figure R**.



## Step 8 Throwing away (disposing of) your OTULFI pre-filled pen

Used OTULFI pre-filled pen and clear cap should be placed in a puncture-resistant container, like a sharps container, right away after use (see **Figure R**).

**Do not** put the clear cap back on the OTULFI pre-filled pen.

**Do not** throw away (dispose of) your OTULFI pre-filled pen in your household trash.

Any unused medicinal product or waste material and the sharps container should be disposed of in accordance with local requirements.

Antiseptic wipes and other supplies can be disposed of in your garbage.

**Always keep the sharps disposal container out of reach of children. Keep OTULFI pre-filled pen and all medicines out of the reach of children.**

