

Instructions for Use on reverse side

Package leaflet: Information for the user

Otufi® 45 mg solution for injection in pre-filled pen ustekinumab

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

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

This leaflet has been written for the person taking the medicine.

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

What is in this leaflet

1. What Otufi is and what it is used for
2. What you need to know before you use Otufi
3. How to use Otufi
4. Possible side effects
5. How to store Otufi
6. Contents of the pack and other information

1. What Otufi is and what it is used for

What Otufi is

Otufi contains the active substance 'ustekinumab', a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

Otufi belongs to a group of medicines called 'immunosuppressants'. These medicines work by weakening part of the immune system.

What Otufi is used for

Otufi administered using pre-filled pen is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults
- Psoriatic arthritis - in adults
- Moderate to severe Crohn's disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis

Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails. Otufi will reduce the inflammation and other signs of the disease.

Otufi administered using pre-filled pen is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

Psoriatic arthritis

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

- Reduce the signs and symptoms of your disease.
- Improve your physical function.
- Slow down the damage to your joints.

Crohn's disease

Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Otufi to reduce the signs and symptoms of your disease.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis, you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Otufi to reduce the signs and symptoms of your disease

2. What you need to know before you use Otufi

Do not use Otufi

- If you are allergic to ustekinumab or any of the other ingredients of this medicine (listed in section 6).
- If you have an active infection which your doctor thinks is important.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Otufi.

Warnings and precautions

Talk to your doctor or pharmacist before using Otufi. Your doctor will check how well you are before each treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have Otufi. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects

Otufi can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking Otufi. See 'Serious side effects' in section 4 for a full list of these side effects.

Before you use Otufi tell your doctor:

- If you ever had an allergic reaction to ustekinumab. Ask your doctor if you are not sure.
- If you have ever had any type of cancer - this is because immunosuppressants like Otufi weaken part of the immune system. This may increase the risk of cancer.
- If you have been treated for psoriasis with other biologic medicines (a medicine produced from a biological source and usually given by injection) - the risk of cancer may be higher.
- If you have or have had a recent infection.
- If you have any new or changing lesions within psoriasis areas or on normal skin.
- If you have ever had an allergic reaction to Otufi injection -See 'Look out for serious side effects' in section 4 for the signs of an allergic reaction.
- If you are having any other treatment for psoriasis and/or psoriatic arthritis - such as another immunosuppressant or phototherapy (when your body is treated with a type of ultraviolet (UV) light). These treatments may also weaken part of the immune system. Using these therapies together with Otufi has not been studied. However it is possible it may increase the chance of diseases related to a weaker immune system.
- If you are having or have ever had injections to treat allergies - it is not known if Otufi may affect these.
- If you are 65 years of age or over - you may be more likely to get infections.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Otufi.

Some patients have experienced lupus-like reactions including skin lupus or lupus-like syndrome during treatment with ustekinumab. Talk to your doctor right away if you experience a red, raised, scaly rash sometimes with a darker border, in areas of the skin that are exposed to the sun or with joint pains.

Heart attack and strokes

Heart attack and strokes have been observed in a study in patients with psoriasis treated with ustekinumab. Your doctor will regularly check your risk factors for heart disease and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or abnormal sensation on one side of your body, facial droop, or speech or visual abnormalities.

Children and adolescents

The Otufi pre-filled pen is not recommended for use in children and adolescents under 18 years of age with psoriasis or Crohn's disease because it has not been studied in this age group. The pre-filled syringe or vial should be used instead for children 6 years of age and older and adolescents with psoriasis. The solution for infusion, pre-filled vial or syringe should be used instead for children weighing at least 40 kg with Crohn's disease.

Otufi is not recommended for use in children and adolescents under 18 years of age with psoriatic arthritis, or ulcerative colitis or children with Crohn's disease who weigh less than 40 kg because it has not been studied in this age group.

Other medicines, vaccines and Otufi

Tell your doctor or pharmacist:

- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Otufi.
- If you received Otufi while pregnant, tell your baby's doctor about your Otufi treatment before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis). Live vaccines are not recommended for your baby in the first twelve months after birth if you received Otufi during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- A higher risk of birth defects has not been seen in babies exposed to ustekinumab in the womb. However, there is limited experience with ustekinumab in pregnant women. It is therefore preferable to avoid the use of Otufi in pregnancy.
- If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Otufi and for at least 15 weeks after the last Otufi treatment.
- Ustekinumab can pass across the placenta to the unborn baby. If you received Otufi during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals if you received Otufi during your pregnancy before the baby receives any vaccine. Live vaccines such as the BCG vaccine (used to prevent tuberculosis) are not recommended for your baby in the first twelve months after birth if you received Otufi during the pregnancy unless your baby's doctor recommends otherwise.
- Ustekinumab may pass into breast milk in very small amounts. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you should breast-feed or use Otufi - do not do both.

Driving and using machines

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

Otufi contains polysorbate 80

This medicine contains 0.02 mg of polysorbate 80 in each pre-filled pen of 0.5 mL which is equivalent to 0.04 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Otufi

Otufi is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Otufi is intended. Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

How much Otufi is given

Your doctor will decide how much Otufi you need to use and for how long.

Adults aged 18 years or older

Psoriasis or Psoriatic Arthritis

- The recommended starting dose is 45 mg Otufi. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or Ulcerative Colitis

- During treatment, the first dose of approximately 6 mg/kg Otufi will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg Otufi after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg Otufi may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

How Otufi is given

- Otufi is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject Otufi.
- However, you and your doctor may decide that you may inject Otufi yourself. In this case you will get training on how to inject Otufi yourself.
- For instructions on how to inject Otufi, see 'Instructions for administration' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more Otufi than you should

If you have used or been given too much Otufi, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use Otufi

If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using Otufi

It is not dangerous to stop using Otufi. However, if you stop, your symptoms may come back. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Some patients may have serious side effects that may need urgent treatment.

**Allergic reactions - these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs.**

- Serious allergic reactions ('anaphylaxis') are rare in people taking ustekinumab (may affect up to 1 in 1,000 people). Signs include:
  - difficulty breathing or swallowing
  - low blood pressure, which can cause dizziness or light-headedness
  - swelling of the face, lips, mouth or throat.
- Common signs of an allergic reaction include skin rash and hives (these may affect up to 1 in 100 people).

**In rare cases, allergic lung reactions and lung inflammation have been reported in patients who receive ustekinumab. Tell your doctor right away if you develop symptoms such as cough, shortness of breath, and fever.**

If you have a serious allergic reaction, your doctor may decide that you should not use Otufi again.

**Infections - these may need urgent treatment. Tell your doctor straight away if you notice any of the following signs.**

- Infections of the nose or throat and common cold are common (may affect up to 1 in 10 people)
- Infections of the chest are uncommon (may affect up to 1 in 100 people)
- Inflammation of tissue under the skin ('cellulitis') is uncommon (may affect up to 1 in 100 people)
- Shingles (a type of painful rash with blisters) are uncommon (may affect up to 1 in 100 people)

Otufi may make you less able to fight infections. Some infections could become serious and may include infections caused by viruses, fungi, bacteria (including tuberculosis), or parasites, including infections that mainly occur in people with a weakened immune system (opportunistic infections). Opportunistic infections of the brain (encephalitis, meningitis), lungs, and eye have been reported in patients receiving treatment with ustekinumab.

You must look out for signs of infection while you are using Otufi. These include:

- fever, flu-like symptoms, night sweats, weight loss
- feeling tired or short of breath; cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning when passing water
- diarrhoea
- visual disturbance or vision loss
- headache, neck stiffness, light sensitivity, nausea or confusion.

Tell your doctor straight away if you notice any of these signs of infection. These may be signs of infections such as chest infections, skin infections, shingles or opportunistic infections that could have serious complications. Tell your doctor if you have any kind of infection that will not go away or keeps coming back. Your doctor may decide that you should not use Otufi until the infection goes away. Also tell your doctor if you have any open cuts or sores as they might get infected.

**Shedding of skin - increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should tell your doctor straight away if you notice any of these signs.**

Other side effects

Common side effects (may affect up to 1 in 10 people):

- Diarrhoea
- Nausea
- Vomiting
- Feeling tired
- Feeling dizzy
- Headache
- Itching ('pruritus')
- Back, muscle or joint pain
- Sore throat
- Redness and pain where the injection is given
- Sinus infection

Uncommon side effects (may affect up to 1 in 100 people):

- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked or stuffy nose
- Bleeding, bruising, hardness, swelling and itching where the injection is given
- Feeling weak
- Drooping eyelid and sagging muscles on one side of the face ('facial palsy' or 'Bell's palsy'), which is usually temporary
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1 000 people)

- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10,000 people)

- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid).
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Otufi

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2 °C - 8 °C). Do not freeze.
- Keep the pre-filled pen in the outer carton in order to protect from light.
- If needed, individual Otufi pre-filled pens 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 in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator in the space provided on the outer carton. At any time before the end of this period, the product can be put back in the refrigerator once and kept there until the expiry date. Discard the pre-filled pen if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake Otufi pre-filled pens. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:

- After the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see section 6 'What Otufi looks like and contents of the pack').
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.

Otufi is for single use only. Any unused product remaining in the pen should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Otufi contains

- The active substance is ustekinumab. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL.
- The other ingredients are L-histidine, polysorbate 80 (E433), sucrose, water for injections and hydrochloric acid (to adjust pH).

What Otufi looks like and contents of the pack

Otufi is a clear, colourless to slightly brown-yellow solution for injection. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled pen. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL of solution for injection.

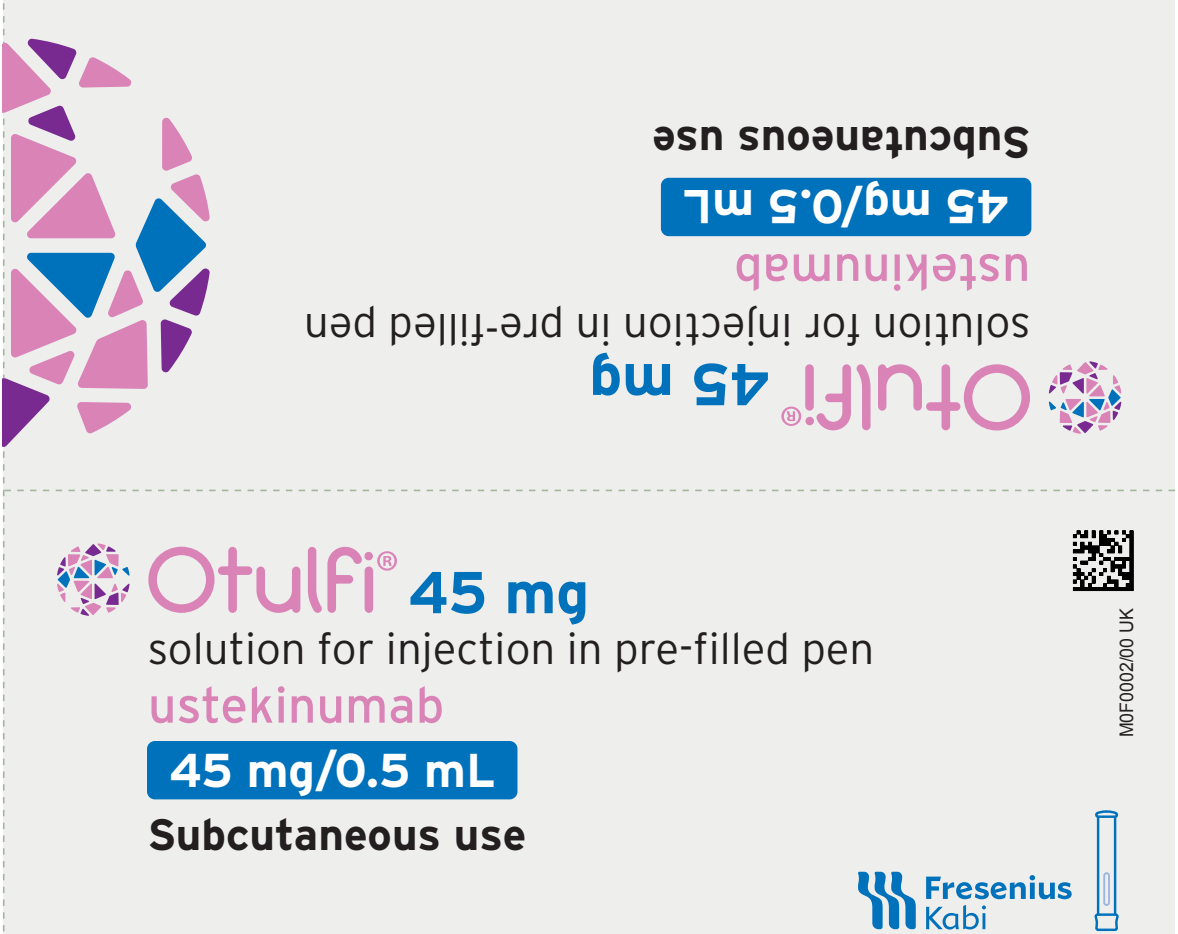
Marketing Authorisation Holder

Fresenius Kabi Limited  
Cestrian Court  
Eastgate Way, Manor Park  
Runcorn, Cheshire, WA7 1NT  
United Kingdom

Manufacturer

Fresenius Kabi Austria GmbH  
Hafnerstraße 36  
8055 Graz  
Austria

This leaflet was last revised in May 2026.



## Instructions for use

### Otulf 45 mg solution for injection in pre-filled pen

ustekinumab

This "Instructions for Use" contains information on how to inject OTULFI using the 45 mg/0.5 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

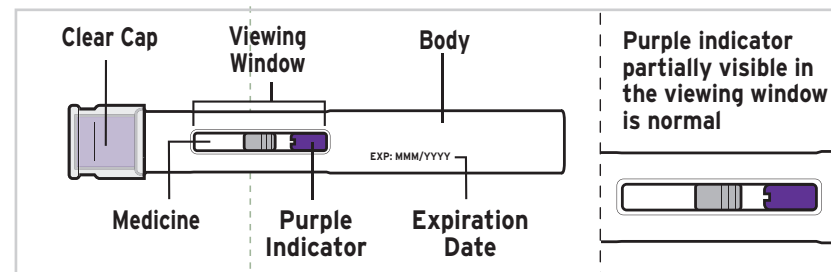
- Read the package leaflet that comes with your OTULFI pre-filled pen for important information you need to know before using it.
- For subcutaneous injection only** (inject directly under the skin).
- If your doctor decides that you or a caregiver can give your OTULFI injection at home, you should receive 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

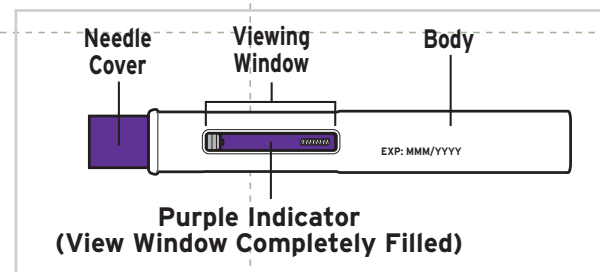
- Store OTULFI pre-filled pens in the refrigerator between 2°C to 8°C.
- Store unused OTULFI pre-filled pens in the original carton to protect from light.
- Do not** freeze OTULFI pre-filled pen. Do not use OTULFI pre-filled pen if it was frozen.
- Do not** expose OTULFI pre-filled pen to heat or direct 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

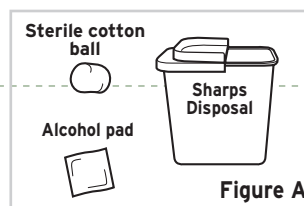


### After Use



## 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 9**)
- Remove the carton containing the OTULFI pre-filled pen from the refrigerator.



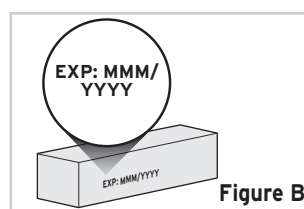
Before you start, check the carton to make sure that it is the right medicine and dose. You will have either a 45 mg dose or 90 mg dose as prescribed by your doctor.

- If your dose is 45 mg, you will receive one 45 mg OTULFI pre-filled pen.
- If your dose is 90 mg, you will receive either one 90mg OTULFI pre-filled pen or two 45 mg OTULFI pre-filled pens.

#### If you receive two 45 mg OTULFI pre-filled pens for a 90 mg dose:

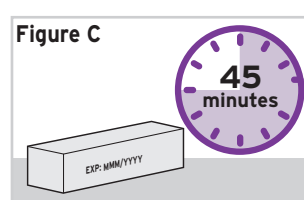
- Follow **Steps 1 through 7** for both injections.
- Choose two different sites for these injections** (for example one injection in the right thigh and the other injection in the left thigh) and give the injections one right after the other.

- 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**).

**Note:** It is normal to see the purple indicator partially visible in the viewing window.

**Do not** use if the OTULFI pre-filled pen shows signs of damage or if it has been dropped.

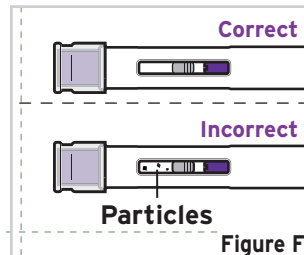
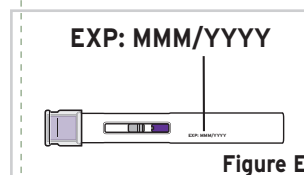
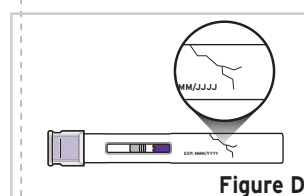
- Check the OTULFI pre-filled pen label to make sure that:
  - The name on the pre-filled pen says OTULFI.
  - The dose on the OTULFI pre-filled pen is what you are prescribed.
  - The expiration date (EXP) on the OTULFI pre-filled pen has not passed (see **Figure E**).

**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**).



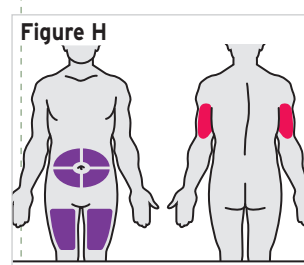
## Step 4 Choose the injection site

- 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 9**).

**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**).
- Look at the viewing window to make sure that the purple indicator is moving during the injection.

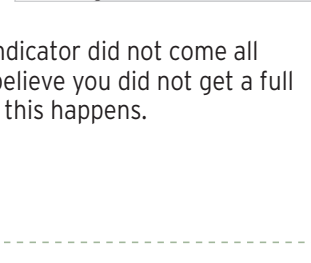
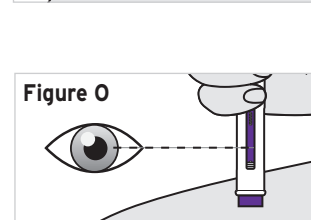
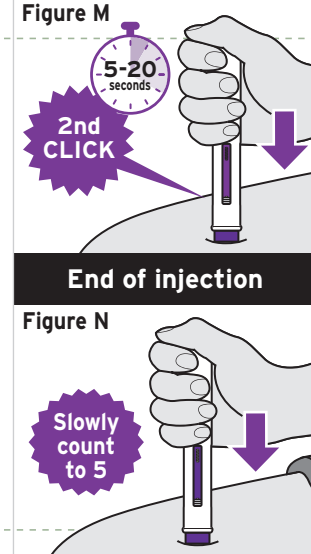
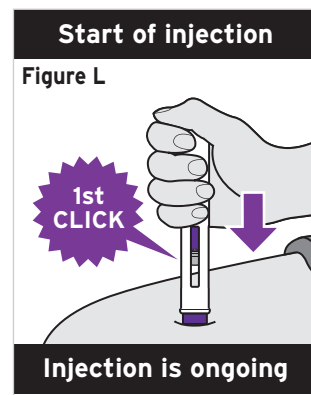
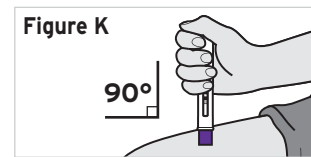
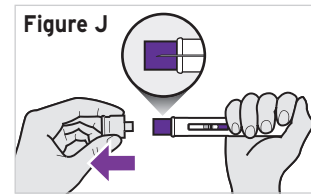
- Continue pushing the OTULFI pre-filled pen down on the injection site and listen for a **second click** which means that the injection is almost complete. This may take between **5 to 20 seconds** (see **Figure M**).

**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**).

- 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**).

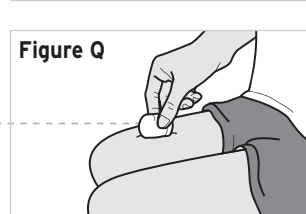
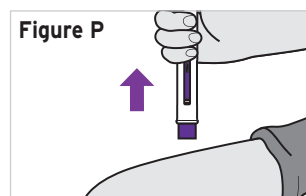
**Note:** The purple needle cover will slide down and cover the needle.

**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 9** and **Figure R**.



## Step 8 If a second 45 mg injection is needed for a 90 mg dose, repeat Steps 1 through 7

**If you receive two 45 mg OTULFI pre-filled pens for a 90 mg dose, give the second injection right after the first.**

- Repeat **Steps 1 through 7** with the second OTULFI pre-filled pen.
- Choose two different sites for these injections** (for example one injection in the right thigh and the other injection in the left thigh) and give the injections one right after the other.

## Step 9 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 waste.

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.**

