Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Hulio®

Solution for injection in a pre-filled syringe, 40 mg/0.8 ml (50 mg/ml)

Each **Hulio** pre-filled syringe contains:
Adalimumab 40 mg/0.8 ml

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".
Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is the same as yours.

In addition to the leaflet, the **Hulio** product has a Patient Safety Information Card. This card includes important safety information, which you should know before starting the treatment and during the treatment with **Hulio** and act accordingly. Read the Patient Safety Information Card and the patient leaflet before using the medicine. Keep the card for further reference if needed.

Hulio is a bio-similar product. For further information about bio-similar products refer to the Ministry of Health:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx

1. What is the medicine intended for?

Hulio is intended for the treatment of:
- Active rheumatoid arthritis, moderate to severe, in adults, when other accepted treatment has not succeeded.
- Severe rheumatoid arthritis, active and progressive in adults who have not been previously treated with methotrexate.
- Severe and active ankylosing spondylitis, in adults, when other accepted treatment has not succeeded.
- Severe axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults, when there was an inadequate response to or intolerance to non-steroidal anti-inflammatory drugs (NSAIDs).
- Active and progressive psoriatic arthritis, in adults, when other accepted treatment has not succeeded.
- Moderate to severe plaque psoriasis in adults who are candidates for systemic treatment.
- Active Crohn's disease, moderate to severe, in adults, when other accepted treatment has not succeeded, or has been unsuitable.
- Moderate to severe ulcerative colitis in adults, when other accepted treatment has not succeeded, or in patients who cannot receive other accepted treatments.
- Moderate to severe active hidradenitis suppurativa in adults, when other accepted treatment has not succeeded.
- Intestinal Behcet's disease, when other accepted treatment has not succeeded.
- Uveitis – inflammation of the uvea (panuveitis, posterior or intermediate), from a non-infectious source, in adults, when treatment with steroids is unsuitable or inadequate.

Therapeutic group: TNF blocker.

Hulio contains the active ingredient adalimumab.
The active ingredient in **Hulio**, adalimumab, is a human monoclonal antibody.
Monoclonal antibodies are proteins that attach to specific targets.
The target of adalimumab is a protein called tumour necrosis factor (TNFα), which is involved in the immune (defense) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, **Hulio** decreases the process of inflammation in these diseases.

Hulio is not intended for children and adolescents under 18 years of age.

2. Before using the medicine

Do not use the medicine if:
- you are hypersensitive (allergic) to the active ingredient (adalimumab) or to any of the other ingredients this medicine contains (see section 6).
- you have active tuberculosis or other severe infections (see "Special warnings regarding the use of the medicine"). It is important you tell your doctor if you have symptoms of infections, such as fever, wounds, feeling tired and dental problems.
- you have moderate or severe heart failure. It is important to tell your doctor if you have or have had a serious heart condition (see "Special warnings regarding the use of the medicine").

Special warnings regarding the use of the medicine
Before treatment with Hulio, tell your doctor:
Allergic reactions
- If you have allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or a rash, do not inject more **Hulio** and contact your doctor immediately since in rare cases these reactions can be life-threatening.

Infections
- If you have an infection, including long-term infection or a local infection (e.g. leg ulcer), consult your doctor before using **Hulio**. If you are unsure, contact your doctor.
- You may get infections more easily during treatment with **Hulio**. This risk may worsen if you have health problems. These infections may be serious and include:
  - tuberculosis
  - infections caused by viruses, fungi, parasites or bacteria
  - severe infections in the blood (sepsis)

In rare cases, these infections may be life-threatening. It is important to tell your doctor if symptoms appear, such as fever, wounds, feeling tired or dental problems. Your doctor may recommend you stop the treatment with **Hulio** temporarily.
- Consult your doctor if you live or travel in areas where fungal infections are very common (such as histoplasmosis, coccidioidomycosis or blastomycosis).
- Consult your doctor if you have had recurring infections or other conditions that increase the risk of infections.
- If you are over 65 years of age, you may be more sensitive to infections during treatment with **Hulio**. Your doctor and you should pay special attention to signs of infection while receiving treatment with **Hulio**. It is important to tell your doctor if symptoms of infections appear such as fever, sores, feeling tired or dental problems

Tuberculosis
- It is very important that you tell your doctor if you have ever had tuberculosis or if you have been in close contact with someone who has had tuberculosis. If you have active tuberculosis do not use **Hulio**.
- As cases of tuberculosis have been reported in patients treated with **Hulio**, your doctor will check you for signs or symptoms of tuberculosis before starting treatment with **Hulio**. This will include a thorough medical evaluation, including your medical history and suitable screening tests (such as, a chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your "**Patient Safety Information Card**".
- Tuberculosis can develop during therapy even if you have received treatment for the prevention of tuberculosis.
- Refer to your doctor immediately, if symptoms of tuberculosis appear (such as a persistent cough, weight loss, lack of energy, mild fever), or of any other infection during or after treatment with **Hulio**.

Hepatitis B
- Tell your doctor if you are a carrier of the hepatitis B virus (HBV), if you have active HBV or if you think you might be at risk of getting HBV.
- Your doctor should test you for HBV. In people who carry HBV, **Hulio** may reactivate the virus.
- In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV can be life threatening.

Surgery or dental procedure
- If you are about to have surgery or dental procedures, tell your doctor that you are taking **Hulio**. Your doctor may recommend temporary discontinuation of **Hulio**.

Diseases involving demyelinating processes
- If you have or develop a disease involving demyelinating processes (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if you should receive or continue to receive **Hulio**. Tell your doctor immediately if you experience symptoms like changes in vision, weakness in your arms or legs or numbness or tingling in any part of the body.

Vaccinations
- Certain vaccines may cause infections and should not be received during treatment with **Hulio**.
- Consult your doctor before you receive any vaccines.
- If you were treated with **Hulio** while you were pregnant, your baby may be at a higher risk for getting an infection during the five months after the last dose you received during pregnancy. It is important to tell the doctors and the staff caring for your baby that you were treated with **Hulio** during pregnancy, so they can decide when your baby can receive vaccines.

Heart failure
- If you have mild heart failure and are being treated with **Hulio**, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have or have had a serious heart condition. If new symptoms of heart failure develop or if existing symptoms worsen (e.g.: shortness of breath, or swelling of the feet), contact your doctor immediately. Your doctor will decide if you should receive **Hulio**.

Fever, bruising, bleeding or paleness
- In some patients the body fails to produce enough of the blood cells that fight off infections or help to stop bleeding. Your doctor may decide to stop the treatment. If you develop a fever that does not go away, light bruises, if you bleed very easily, or if you look very pale, contact your doctor right away.

Cancer
- There have been very rare cases of certain kinds of cancer in adults and children treated with adalimumab or other TNF blockers.
- People with more serious rheumatoid arthritis who have had the disease for a long time, may have a higher than average risk of getting lymphoma (a cancer that affects the lymph system) and leukemia (a cancer that affects the blood and bone marrow).
- If you are being treated with **Hulio**, the risk of getting lymphoma, leukemia, or another type of cancer may increase. On rare occasions, an uncommon and severe type of lymphoma has been seen in patients taking adalimumab. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
- Tell your doctor if you are taking azathioprine or 6-mercaptopurine together with **Hulio**.
- Cases of non-melanoma skin cancer have been observed in patients taking adalimumab.
- Tell your doctor if new skin lesions appear during or after treatment or if there is a change in existing lesions.
- There have been cases of cancers other than lymphoma reported in patients who took a different TNF inhibitor and have a specific type of lung disease called chronic obstructive pulmonary disease (COPD). If you have COPD, or you are a heavy smoker, consult your doctor as to whether treatment with a TNF blocker is suitable for you.

Autoimmune disease
- On rare occasions, treatment with **Hulio** can result in a lupus-like syndrome. Refer to your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness appear.

Children and adolescents
Hulio is not intended for use in children and adolescents under 18 years of age.

Drug Interactions
If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Do not take **Hulio** with medicines containing the following active ingredients due to an increased risk of serious infections:
- anakinra
- abatacept

These medicines are used to treat rheumatoid arthritis.
Hulio can be taken together with:
- methotrexate
- certain disease-modifying anti-rheumatic agents (such as sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations)
- steroids or pain medication, including non-steroidal anti-inflammatory drugs (NSAIDs)

If you have questions, ask your doctor.

Pregnancy and breastfeeding
- You should consider the use of suitable contraception to prevent pregnancy and continue its use for at least 5 months after the last **Hulio** treatment.
- If you are pregnant, think you may be pregnant or are planning to become pregnant, consult your doctor about taking this medicine.
- **Hulio** will only be used during pregnancy if necessary.
- In a study examining the use in pregnant women, no higher risk of birth defects was found when the mother received adalimumab during pregnancy compared to mothers with the same disease who did not receive adalimumab.
- **Hulio** can be taken while breastfeeding.
- If you received **Hulio** during pregnancy, your baby may be at higher risk of developing infections.
- It is important to tell the pediatrician and medical staff at the clinic and the Family Health Center (Tipat Halav) that you took **Hulio** during pregnancy, before the baby receives any vaccine. For more information on vaccines, see the section "Special warnings regarding the use of the medicine".

Driving and using machines
Hulio may have a small effect on the ability to drive, ride a bicycle or operate machines. After treatment with **Hulio**, dizziness and vision disturbances may occur.

Smoking
If you are a heavy smoker, consult your attending doctor as to whether treatment with a TNF blocker is suitable for you (for further information, see the section "Special warnings regarding the use of the medicine").

Important information about some of the ingredients of this medicine
Every pre-filled syringe of **Hulio** contains 38.2 mg sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance for some sugars or if you have been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which a person cannot break down fructose, consult your doctor before using this medicine.
This medicine contains less than 1 mmol of sodium (23 mg) per pre-filled syringe, i.e., it is essentially "sodium-free".

3. How to use this medicine

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the attending doctor only.
Do not exceed the recommended dose.

Method of administration
A **Hulio** pre-filled syringe is injected under the skin (subcutaneous use).
Detailed instructions on how to inject Hulio are provided in section 7 "Instructions for use".

If you have accidentally taken a higher dosage
If you have accidentally injected **Hulio** more frequently than instructed by your doctor or pharmacist, call your doctor or pharmacist and inform them about it. Always take the package of the medicine with you, even if it is empty.

If you forgot to inject Hulio
If you forgot to inject **Hulio**, inject the next dose as soon as you remember. Take the next dose as originally planned, had you not forgotten a dose. Continue with the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking Hulio
Discuss stopping to take **Hulio** with your doctor. Your symptoms may return if you stop taking **Hulio**.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Hulio** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Most of the side effects are mild to moderate. However, some of the side effects may be serious and require treatment.
Side effects may occur up to at least 4 months after the last **Hulio** treatment.

Refer to your doctor immediately if you notice any of the following symptoms:
- severe rash, hives or other signs of an allergic reaction
- swollen face, hands, feet
- trouble breathing, trouble swallowing
- shortness of breath with physical activity or upon lying down or swelling of the feet

Refer to your doctor as soon as possible if you notice any of the following symptoms:
- signs of infection, such as fever, feeling sick, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- bruising or an open sore that does not heal
- signs and symptoms indicating circulatory system disorders such as persistent fever, bruising, bleeding, paleness

The symptoms described above can be signs of the following side effects, which have been observed with adalimumab.

Very common side effects (effects that appear in more than 1 in 10 users):
- injection site reactions (including pain, swelling, redness or itching)
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia)
- headache
- abdominal pain
- nausea and vomiting
- rash
- musculoskeletal pain

Common side effects (effects that appear in 1-10 out of 100 users):
- serious infections (including blood poisoning and influenza)
- intestinal infections (including gastroenteritis)
- skin infections (including cellulitis, shingles)
- ear infections
- oral infections (including tooth infections and cold sores)
- reproductive tract infections
- urinary tract infection
- fungal infections
- joint infections
- benign tumours
- skin cancer
- allergic reactions (including seasonal allergy)
- dehydration
- mood swings (including depression)
- anxiety
- difficulty sleeping
- sensation disorders such as tingling, prickling or numbness
- migraine
- nerve root compression (including low back pain and leg pain)
- vision disturbances
- eye inflammation
- inflammation of the eye lid and swelling of the eye
- vertigo (feeling of dizziness)
- sensation of heart beating rapidly
- high blood pressure
- flushing
- hematoma (accumulation of blood outside of blood vessels)
- cough
- asthma
- shortness of breath
- gastrointestinal bleeding
- digestive disorder (indigestion, bloating, heart burn)
- acid reflux
- sicca syndrome (including dry eyes and dry mouth)
- itching
- itchy rash
- bruising
- inflammation of the skin (such as eczema)
- breaking of fingernails and toenails
- increased sweating
- hair loss
- new onset or worsening of psoriasis
- muscle spasms
- blood in urine
- kidney problems
- chest pain
- oedema (swelling)
- fever
- reduction in blood platelets which increases risk of bleeding or bruising
- impaired healing

Uncommon side effects (effects that appear in 1-10 out of 1,000 users):
- opportunistic infections (which include tuberculosis and other infections that occur when the body's resistance to diseases is lowered)
- nervous system infections (including viral meningitis)
- eye infections
- bacterial infections
- diverticulitis (infection and inflammation of the large intestine)
- cancer
- cancer that affects the lymph system
- melanoma
- immune system disorders that may affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- inflammation of blood vessels (vasculitis)
- tremor
- peripheral nerve disease (neuropathy)
- stroke
- hearing loss, hearing buzzing
- sensation of irregular heart beat such as a skipped beat
- heart problems that can cause shortness of breath or ankle swelling
- heart attack
- formation of a sac in the wall of a major artery, inflammation and clot in a vein, blockage of a blood vessel
- lung diseases that cause shortness of breath (including inflammation)
- pulmonary embolism (blockage of an artery in a lung)
- abnormal accumulation of fluid in the pleural cavity (pleural effusion)
- inflammation of the pancreas which causes serious pain in the abdomen and back
- difficulty in swallowing
- facial edema (swelling of the face)
- gallbladder inflammation, gallbladder stones
- fatty liver
- night sweats
- scarring
- abnormal muscle tissue breakdown
- systemic lupus erythematosus (including inflammation of the skin, heart, lung, joints and other organs)
- sleep interruptions
- impotence
- inflammations

Rare side effects (effects that appear in 1-10 out of 10,000 users):
- leukemia (cancer affecting the blood and bone marrow)
- severe allergic reaction with shock
- multiple sclerosis
- nerve disorders (such as inflammation of the optic nerve and Guillain-Barré syndrome that may cause muscle weakness, sensory impairment, tingling sensation in the arms and upper body)
- heart stops pumping
- scarring of the lung
- intestinal perforation (hole in the intestine)
- hepatitis
- reactivation of viral hepatitis B
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system)
- inflammation of blood vessels in the skin (cutaneous vasculitis)
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash)
- facial oedema (swelling of the face) as an allergic reaction
- erythema multiforme (inflammatory skin rash)
- lupus-like syndrome
- angioedema (localized swelling of the skin)
- lichenoid skin reaction (itchy, reddish-purple skin rash)

Side effects of unknown frequency (frequency cannot be estimated from the available data):
- lymphoma of the T-cell in the liver and spleen (a rare blood cancer that is often fatal)
- Merkel cell carcinoma (a type of skin cancer)
- Kaposi's sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi's sarcoma most commonly appears as purple lesions on the skin
- liver failure
- worsening of dermatomyositis (looks like a skin rash accompanying muscle weakness)
- Weight gain (for most patients, the weight gain was small)

Some of the side effects, observed with the use of the medicine, have no symptoms and can only be discovered through blood tests, including:

Very common side effects (effects that appear in more than 1 in 10 users):
- low levels of white blood cells
- low levels of red blood cells
- increase in blood lipids
- increase in liver enzymes

Common side effects (effects that appear in 1-10 out of 100 users):
- high levels of white blood cells
- low levels of platelets
- increase in uric acid in the blood
- abnormal levels of sodium in the blood
- low levels of calcium in the blood
- low levels of phosphate in the blood
- high blood sugar
- high levels of lactate dehydrogenase in the blood
- presence of autoantibodies in the blood
- low levels of potassium in the blood

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):
- elevated bilirubin values (liver function blood test)

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- low levels of white blood cells, red blood cells and platelets

If a side effect appears if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:
https://sideeffects.health.gov.il

5. How to store the medicine

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) appearing on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store in a refrigerator (2°C-8°C). Do not freeze. Keep the syringe in the outer carton package to protect from light.
  When needed (e.g., when you are travelling), **one** pre-filled syringe can be stored at a temperature below 25°C for a maximum period of 14 days – protect the syringe from light.
  After taking the syringe out of the refrigerator and transferring it to storage at a temperature below 25°C, **the syringe must be used within 14 days or discarded**, even if it is returned to the refrigerator.
  Record the date the syringe is first removed from refrigerator and the date after which the syringe should be discarded.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sorbitol, monosodium glutamate, polysorbate 80, methionine, water for injections (distilled), hydrochloric acid

What does the medicine look like and the contents of the package
The package contains **Hulio** solution for injection in a pre-filled syringe. The solution is clear to slightly opalescent, colourless to pale brownish-yellow.
Approved package sizes:
- 1 pre-filled syringe with 2 alcohol pads.
- 2 pre-filled syringes with 2 alcohol pads.
- 6 pre-filled syringes with 6 alcohol pads.

Not all package sizes may be marketed.

Hulio is approved in the following forms: pre-filled syringe, pre-filled pen.

Manufacturer name and address: Terumo Yamaguchi D&D Corporation, Sayama, Japan

Revised in August 2021 according to MOH guidelines

Drug registration number at the national drug registry of the Ministry of Health: 167-87-36610-00

Registration holder: Dexcel® Ltd.
1 Dexcel St., Or Akiva 3060000, Israel

7. Instruction for use

Read the instructions carefully and follow them step by step. First, your doctor, nurse or other medical staff member will show you how to inject **Hulio** pre-filled syringe. Ask your doctor or nurse if there is anything you do not understand.

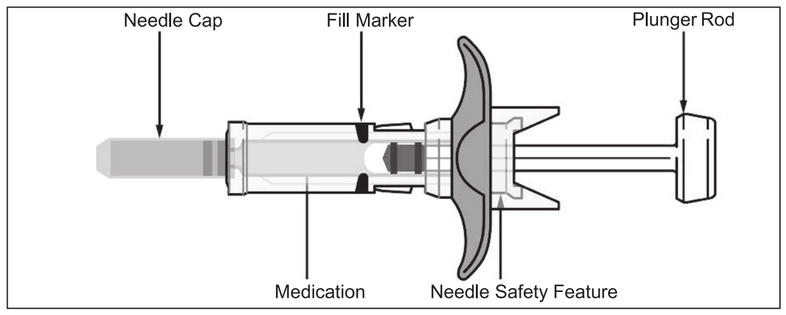
Do not attempt to self-inject until you are sure that you understand how to prepare and administer the injection. After proper training, the injection can be self-administered or given by another person, for example a family member or carer.

Each pre-filled syringe is used for one injection only and contains adalimumab 40 mg.
Do not mix the **Hulio** solution with another medicine.
To help you remember which day/days of the week you should inject **Hulio**, you can make a note on a calendar or in a diary.

Before you start
Find a quiet place with a well-lit, clean and flat work surface and gather all the supplies you will need to give yourself or receive the injection:
- 1 pre-filled syringe
- 1 alcohol pad
- 1 sharps disposal container (not included in **Hulio** pack)
- 1 gauze pad or cotton ball (not included in **Hulio** pack)

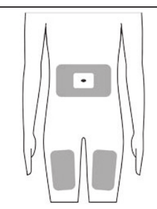
If you do not have all the necessary supplies, refer to the nurse or pharmacist.

Preparing the pre-filled syringe
The pre-filled syringes should be stored in the refrigerator (2°C- 8°C).
- Take one syringe out of the refrigerator at least 30 minutes before you intend to use it to allow its contents to reach room temperature.
  - **Do not** use other heat sources such as a microwave oven or hot water to warm the syringe.
  - **Do not** put the syringe back in the refrigerator after it has reached room temperature.
- Check the expiry date printed on the syringe.
  - **Do not** use the syringe after the expiry date.
- Check the syringe to make sure the medicine is at or near the Fill Marker (you may need to shake gently to see the fluid), and the fluid is clear or slightly opalescent, colourless to pale brownish-yellow and does not contain particles.
  - **Do not** use the syringe if the medication is not near the Fill Marker.
  - **Do not** use the syringe if the liquid is cloudy, its colour has changed, or if it contains particles.



Injection steps
Follow these steps every time you use a **Hulio** pre-filled syringe:

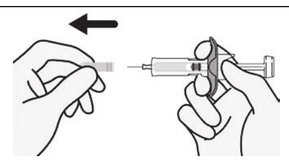
Step 1 - Choose and prepare the injection site
Hulio pre-filled syringe is for subcutaneous injection. It should be injected into the thigh or abdomen.
You should alternate and change the injection site each time, and stay at least 3 cm from the previous injection site.
If you are injecting into the abdomen, choose a site that is at least 5 cm away from the navel.
- **Do not** inject into an area where the skin is red, hard, bruised or tender.
- **Do not** inject into an area with scars or stretch marks.
- If you have psoriasis, **do not** inject into an area where the skin is raised, thick, red, scaly or with lesions.
- **Do not** inject through clothes. Roll back any clothing that may interfere with the injection site.


Abdomen or Thighs

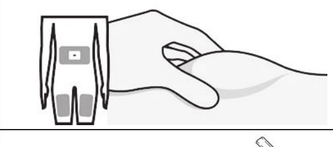
Step 2 - Wash hands
Wash your hands with soap and water.

Step 3 - Prepare the injection site
Wipe the skin at the chosen injection site with an alcohol pad.
- Wait for it to dry on its own, do not dry it.
- **Do not** touch this area again before the injection.

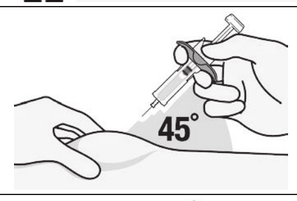
Step 4 - Remove the cap from the needle
Pull the needle cap straight off the syringe. A few drops of fluid may come out of the needle, this is normal. It is also normal to see air bubbles.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** twist or bend the needle cap when removing it, this can harm the needle.
- **Do not** touch the plunger or pull it back at any time.
- **Do not** re-cap the needle and do not touch the needle with your fingers and do not allow the needle to touch anything.
- **Do not** remove air bubbles.
- **Do not** use the syringe if it fell after removal of the needle cap.



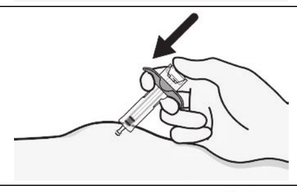
Step 5 - Squeeze and hold the injection site
Gently squeeze the injection site to create a raised area and hold that area firmly.



Step 6 - Insert the needle into the area
At a 45 degrees angle to the injection site, use a quick dart-like motion to insert the needle into the site.
Be careful to insert the needle so that it will not inject into your fingers holding the injection site.



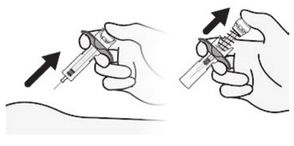
Step 7 - Inject Hulio
After the needle is completely inserted, let go of the site you are squeezing. Slowly push the plunger completely down until **all the medicine is injected** and the syringe is empty.
- If the plunger is not pressed all the way, the safety feature will not activate afterwards to cover the needle.
- **Do not** move or twist the syringe during the injection.



Step 8 - End of injection, remove the syringe
Pull the syringe away from the injection site at the same angle as inserted and release your thumb from the plunger.

Each pre-filled syringe has a safety feature which will cover the needle after release of the plunger. If the needle is not covered, carefully throw the syringe into the sharps disposal container to avoid injury.

After injection, if slight bleeding occurs from the injection site, apply gauze pad or cotton ball gently on the skin for a few seconds – **do not** rub the injection site. If needed cover the area of injection with a bandage (plaster).



Step 9 - Dispose of syringe and cap
Dispose of the used syringe and cap in a sharps disposal container.
Check with a medical staff member for instructions on how to properly dispose of a full container.
- **Do not** re-use the syringe.
- **Do not** put the needle cap back on the needle.
- **Do not** dispose of the sharps disposal container in your household waste.
- **Do not** recycle the sharps disposal container you used.
- Always keep your sharps disposal container out of the sight and reach of children.