PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed with a doctor's prescription only

HUMIRA®

Solution for injection in a pre-filled syringe

Active ingredient and its concentration: adalimumab 100 mg/1 ml
Each Humira 20 mg pre-filled syringe contains:
adalimumab 20 mg/0.2 ml
Each Humira 40 mg pre-filled syringe contains:
adalimumab 40 mg/0.4 ml
Each Humira 80 mg pre-filled syringe contains:
adalimumab 80 mg/0.8 ml
Inactive and allergenic ingredients in the preparation - see section 6 "Further Information" and "Important information about some of the ingredients in the medicine" in section 2 of this leaflet.
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 to treat your ailment/for you. Do not pass it on to others. It may harm them, even if it seems to you that their ailment/medical condition is similar.

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

For your attention, it is important that you make sure you receive the same medicine prescribed to you by your specialist attending doctor each time you receive the medicine at the pharmacy. If the medicine you received looks different than the one you are usually getting or the instructions for use had changed, please turn immediately to the pharmacist to make sure you received the correct medicine. Each replacement or change of dosage of a medicine containing adalimumab (the active ingredient in the medicine) must be done only by the specialist attending doctor. Please check that the commercial name of the medicinal product prescribed to you by your specialist doctor, is identical to the name of the medicine received from the pharmacist.

1) WHAT IS THE MEDICINE INTENDED FOR?

Rheumatoid arthritis
Humira in combination with methotrexate is indicated for:
- The treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate.
- The treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
Humira has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate.
Polyarticular juvenile idiopathic arthritis
Humira in combination with methotrexate is indicated for the treatment of active polyarticular juvenile idiopathic arthritis, in patients from the age of 2 years who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Humira has not been studied in patients aged less than 2 years.
Enthesitis-related arthritis
Humira is indicated for the treatment of active enthesitis-related arthritis in patients, 6 years of age and older, who have had an inadequate response to, or who are intolerant of, conventional therapy.
Ankylosing spondylitis
Humira is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.
Axial spondyloarthritis without radiographic evidence of AS
Humira is indicated for the treatment of adults with severe axial spondyloarthritis without radiographic evidence of AS, but with objective signs of inflammation by radiological and/or laboratory tests including MRI and serum CRP levels, who have had an inadequate response to, or are intolerant to, non-steroidal anti-inflammatory drugs.
Psoriatic arthritis
Humira is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Humira has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease and to improve physical function.
Psoriasis
Humira is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.
Paediatric plaque psoriasis
Humira is indicated for the treatment of severe chronic plaque psoriasis in children and adolescents from 4 years of age who have had an inadequate response to or are inappropriate candidates for topical therapy and phototherapies.
Hidradenitis suppurativa
Humira is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults and adolescents from 12 years of age with an inadequate response to conventional systemic HS therapy.
Crohn's disease
Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Humira is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.
Paediatric Crohn's disease
Humira is indicated for the treatment of moderately to severely active Crohn's disease in paediatric patients from 6 years of age who have had an inadequate response to conventional therapy including primary nutrition therapy and corticosteroid, and/or an immunomodulator, or who are intolerant to or have contraindications for such therapies.
Ulcerative colitis
Humira is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
Paediatric ulcerative colitis
Humira is indicated for the treatment of moderately to severely active ulcerative colitis in paediatric patients from 6 years of age who have had an inadequate response to conventional therapy including corticosteroids and/or 6-mercaptopurine (6-MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.
Uveitis
Humira is indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adult patients who have had an inadequate response to corticosteroids, in patients in need of corticosteroid-sparing, or in whom corticosteroid treatment is inappropriate.
Paediatric uveitis
Humira is indicated for the treatment of chronic non-infectious uveitis in paediatric patients from 2 years of age who have had an inadequate response to or are intolerant to conventional therapy, or in whom conventional therapy is inappropriate.
Intestinal Behcet's disease
Humira is indicated for the treatment of intestinal Behcet's disease in patients who have had an inadequate response to conventional therapy.

Therapeutic group: TNF-α inhibitors.
The active ingredient in Humira, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target. The target of adalimumab is a protein called tumor necrosis factor (TNF-α), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNF-α, Humira decreases the process of inflammation in these diseases.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients included in the medicine (see section 6 "Further Information" and in section 2 "Important information about some of the ingredients in the medicine").
- You have active tuberculosis or other severe infections (see "Special warnings regarding use of the medicine"). It is important that you tell your doctor if you have symptoms of infections, for example, fever, wounds, feeling tired and dental problems.
- You have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Special warnings regarding use of the medicine").

Special Warnings Regarding Use of The Medicine
Before treatment with Humira, tell your doctor:
Allergic reactions
- If you get allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash, do not inject more Humira 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 an infection in one part of the body (for example, a leg ulcer) consult your doctor before starting Humira. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Humira treatment. This risk may increase if you have problems with your lungs. These infections may be serious and include:
  - tuberculosis
  - infections caused by viruses, fungi, parasites or bacteria
  - severe infection in the blood (sepsis)

  In rare cases, these infections can be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may tell you to stop using Humira for some time.
- Tell your doctor if you live or travel in regions where fungal infections (for example, histoplasmosis, coccidioidomycosis or blastomycosis) are very common.
- Tell your doctor if you have had infections which keep coming back or other conditions that increase the risk of infections.
- If you are over 65 years you may be more likely to get infections while taking Humira. You and your doctor should pay special attention to signs of infection while you are being treated with Humira. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, 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 Humira.
  - As cases of tuberculosis have been reported in patients treated with Humira, your doctor will check you for signs and symptoms of tuberculosis before starting Humira. This will include a thorough medical evaluation including your medical history and appropriate screening tests (for example, 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.
  - If symptoms of tuberculosis (for example, cough that does not go away, weight loss, lack of energy, mild fever), or any other infection appear during or after treatment with Humira, tell your doctor immediately.

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, Humira can cause the virus to become active again.
  - 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, please inform your doctor that you are taking Humira. Your doctor may recommend temporary discontinuation of Humira.

Demyelinating disease
- If you have or develop a demyelinating disease (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 Humira. Tell your doctor immediately if you experience symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.

Vaccinations
- Certain vaccines may cause infections and should not be given while receiving Humira.
  - Check with your doctor before you receive any vaccines.
  - It is recommended that children, if possible, be given all the scheduled vaccinations for their age before they start treatment with Humira.
  - If you received Humira while you were pregnant, your baby may be at a higher risk for getting such an infection for up to approximately five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Humira use during pregnancy so they can decide when your baby should receive any vaccine.

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

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

Cancer
- There have been very rare cases of certain kinds of cancer in children and adult patients taking Humira or other TNF blockers.
  - People with more serious rheumatoid arthritis that 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 take Humira, the risk of getting lymphoma, leukemia, or other cancers may increase. On rare occasions, an uncommon and severe type of lymphoma, has been seen in patients taking Humira. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
  - Tell your doctor if you are taking azathioprine or 6-mercaptopurine with Humira.
  - Cases of non-melanoma skin cancer have been observed in patients taking Humira.
  - If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.
- There have been cases of cancers, other than lymphoma in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNF blocker. If you have COPD, or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.

Autoimmune disease
- On rare occasions, treatment with Humira could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Smoking
If you are a heavy smoker, you should consult your attending doctor as to whether treatment with a TNF blocker is appropriate for you (for further information, see the "Special warnings regarding use of the medicine" section).
Children and adolescents
- Vaccinations: if possible, children should be up to date with all vaccinations before using Humira.

There is no information regarding the safety and efficacy of the use of Humira in children under the age of 2.

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 Humira with medicines containing the following active ingredients due to increased risk of serious infection:
- anakinra
- abatacept

These medicines are used for the treatment of rheumatoid arthritis.
Humira can be taken together with:
- methotrexate
- certain disease-modifying anti-rheumatic agents (for example, sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations)
- steroids or pain medications, including non-steroidal anti-inflammatory drugs (NSAIDs).

If you have questions, ask your doctor.
Pregnancy, breastfeeding and fertility
- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Humira treatment.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice about taking this medicine.
- Humira should only be used during a pregnancy if needed.
- According to a pregnancy study, there was no higher risk of birth defects when the mother had received Humira during pregnancy compared with mothers with the same disease who did not receive Humira.
- Humira can be used while breastfeeding.
- If you received Humira during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell the baby's doctors and other health care professionals in the clinic and in the Family Health Center (Tipat-Halav) about your Humira use during your pregnancy before the baby receives any vaccine. For more information on vaccines, see the "Special warnings regarding use of the medicine" section.
- Pre-clinical data on the effect of Humira on fertility are not available.

Driving and using machines
Humira may have a small effect on the ability to drive, cycle or operate machines. After treatment with Humira, dizziness and vision disturbances may occur.
Important information about some of the ingredients in the medicine
Humira contains polysorbate
Humira 20 mg: the medicine contains 0.2 mg of polysorbate 80 in each 20 mg dose.
Humira 40 mg: the medicine contains 0.4 mg of polysorbate 80 in each 40 mg dose.
Humira 80 mg: the medicine contains 0.8 mg of polysorbate 80 in each 80 mg dose.
Polysorbates may cause allergic reactions. Tell the doctor if you or your child has any known allergies.

3) HOW SHOULD YOU USE THE 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 treatment regimen.
The dosage and treatment regimen will be determined by the attending doctor only.
Do not exceed the recommended dose.
Method of administration
Humira is administered by injection under the skin (by subcutaneous injection).
Detailed instructions on how to inject Humira are provided in section 7 'Instructions for use'.
If you accidentally have taken a higher dosage
If you accidentally inject Humira more frequently than instructed by your doctor or pharmacist, call your doctor or pharmacist and tell them about it. Always take the outer carton of the medicine with you, even if it is empty.
If you forgot to inject Humira
If you forgot to inject Humira, you should inject the next dose as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop the medicine treatment without consulting the doctor.
If you stop using Humira
The decision to stop using Humira should be discussed with your doctor. Your symptoms may return if you stop using Humira.
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 further questions regarding the use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Humira 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 side effects are mild to moderate. However, some of them may be serious and require treatment.
Side effects may occur at least up to 4 months after the last Humira treatment.
Tell your doctor immediately if you notice one of the following symptoms:
- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- shortness of breath with physical activity or upon lying down or swelling of the feet

Tell 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
- a bump or an open sore that does not heal
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness

The symptoms described above can be signs of the below listed side effects, which have been observed with Humira.
Very common side effects (effects that occur 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 occur in 1-10 out of 100 users):
- serious infections (including blood poisoning and influenza)
- intestinal infections (including gastroenteritis)
- skin infections (including cellulitis and shingles)
- ear infections
- oral infections (including tooth infections and cold sores)
- reproductive tract infections
- urinary tract infection
- fungal infections
- joint infections
- benign tumors
- 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 eye swelling
- vertigo (feeling of dizziness or spinning)
- sensation of heart beating rapidly
- high blood pressure
- flushing
- hematoma (collection of blood outside of blood vessels)
- cough
- asthma
- shortness of breath
- gastrointestinal bleeding
- dyspepsia (indigestion, bloating, heart burn)
- acid reflux disease
- sicca syndrome (including dry eyes and dry mouth)
- itching
- itchy rash
- bruising
- inflammation of the skin (such as eczema)
- breaking of finger nails and toe nails
- 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 occur in 1-10 out of 1,000 users):
- opportunistic infections (which include tuberculosis and other infections that occur when resistance to disease is lowered)
- neurological infections (including viral meningitis)
- eye infections
- bacterial infections
- diverticulitis (inflammation and infection of the large intestine)
- cancer
- cancer that affects the lymph system
- melanoma
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly presenting as sarcoidosis)
- inflammation of the blood vessels (vasculitis)
- tremor (shaking)
- neuropathy (disorder of the nerves)
- stroke
- hearing loss, buzzing
- sensation of heart beating irregularly such as skipped beats
- heart problems that can cause shortness of breath or ankle swelling
- heart attack
- a sac in the wall of a major artery, inflammation and clot of a vein, blockage of a blood vessel
- lung diseases causing shortness of breath (including inflammation)
- pulmonary embolism (blockage in an artery of the lung)
- abnormal collection of fluid in the pleural space (pleural effusion)
- inflammation of the pancreas which causes severe pain in the abdomen and back
- difficulty in swallowing
- facial oedema (swelling of the face)
- gallbladder inflammation, gallbladder stones
- fatty liver
- night sweats
- scar
- abnormal breakdown of the muscle tissue
- systemic lupus erythematosus (including inflammation of skin, heart, lung, joints and other organ systems)
- sleep interruptions
- impotence
- inflammations

Rare side effects (effects that occur 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 eye nerve inflammation and Guillain-Barré syndrome that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body)
- heart stops pumping
- pulmonary fibrosis (scarring of the lung)
- intestinal perforation (hole in the intestine)
- hepatitis
- reactivation of hepatitis B virus
- 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) associated with allergic reactions
- 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 (effects whose frequency has not yet been determined):
- hepatosplenic T-cell lymphoma (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 a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- weight gain (for most patients, the weight gain was small)

Some side effects observed with the use of the preparation may not have symptoms and may only be discovered through blood tests. These include:
Very common side effects (effects that occur in more than 1 in 10 users):
- low blood measurements for white blood cells
- low blood measurements for red blood cells
- increased lipids in the blood
- elevated liver enzymes

Common side effects (effects that occur in 1-10 out of 100 users):
- high blood measurements for white blood cells
- low blood measurements for platelets
- increased uric acid in the blood
- abnormal blood measurements for sodium
- low blood measurements for calcium
- low blood measurements for phosphate
- high blood sugar
- high blood measurements for lactate dehydrogenase
- autoantibodies present in the blood
- low blood potassium

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

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- low blood measurements for white blood cells, red blood cells and platelet count

If a side effect has occurred, 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 by clicking on the link "Reporting side effects of medical treatment", located at the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5) HOW SHOULD THE MEDICINE BE STORED?

- 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 in order 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. date) appearing on the outer and inner packages and on the syringe. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C: this temperature range is predominant in most household refrigerators).
- Do not freeze.
- Keep the syringe in the outer carton package in order to protect from light.

Alternative storage conditions:
- When needed (for example, when you are travelling), a **single** pre-filled syringe may be stored at a temperature below 25°C for a maximum period of 14 days – be sure to protect it from light.
- Once the syringe is taken out of the refrigerator, and is stored at a temperature of under 25°C, the syringe **must be used within 14 days or discarded**, even if it is returned to the refrigerator.
- You should record the date when the syringe is first removed from refrigerator and the date after which it should be discarded.
- Do not throw away any medicines via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6) FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Mannitol, polysorbate 80 and water for injections.

What does the medicine look like and the contents of the pack?
- The package contains Humira solution for injection in a pre-filled syringe. The solution is a sterile solution of adalimumab in the following volumes:
  - 20 mg/0.2 ml
  - 40 mg/0.4 ml
  - 80 mg/0.8 ml
- Humira pre-filled syringe for injection is a glass syringe.

Humira pre-filled syringe is available in the following packs:
Humira 20 mg solution for injection
- 2 pre-filled syringes (0.2 ml sterile solution), with 2 alcohol pads, in a blister tray.

Humira 40 mg solution for injection
- 1 pre-filled syringe (0.4 ml sterile solution) with 1 alcohol pad, in a blister tray.
- 2 pre-filled syringes (0.4 ml sterile solution), with 2 alcohol pads, in a blister tray.
- 4 pre-filled syringes (0.4 ml sterile solution), with 4 alcohol pads, in a blister tray.
- 6 pre-filled syringes (0.4 ml sterile solution), with 6 alcohol pads, in a blister tray.

Humira 80 mg solution for injection
- 1 pre-filled syringe (0.8 ml sterile solution) with 1 alcohol pad, in a blister tray.

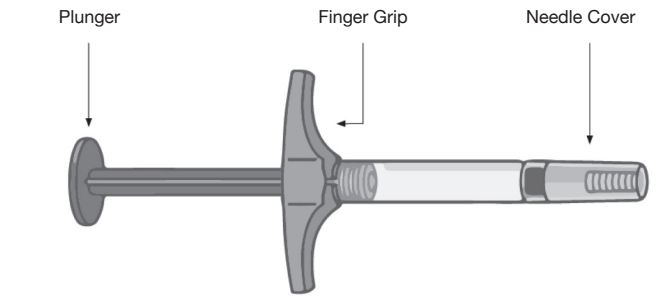
Not all pack sizes and forms may be marketed.
- Humira 20 mg is available in the following forms: a pre-filled syringe.
- Humira 40 mg is available in the following forms: a pre-filled syringe, a pre-filled pen.
- Humira 80 mg is available in the following forms: a pre-filled syringe, a pre-filled pen.
- **License holder and its address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.
- **Manufacturer name and its address:** AbbVie Deutschland GmbH & Co. KG, Knollstrasse 67061, Ludwigshafen, Germany.
- **Revised in December 2025.**
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 157-78-34788

For the sake of simplicity and ease of reading, this leaflet was written as intended for you. Although, the medicine is intended for you or for your child.

7) INSTRUCTIONS FOR USE

- The following instructions explain how to give yourself subcutaneous injection of Humira using the pre-filled syringe.
  First, read all the instructions carefully and then follow them step by step.
- You will be instructed by your doctor, nurse or pharmacist on the technique of self-injection.
- Do not attempt to self-inject the medicine until you are sure that you understand how to prepare and give the injection.
- After proper training, the injection can be given by yourself or given by another person, for example, a family member or friend.
- Only use each pre-filled syringe for one injection.

Humira pre-filled syringe



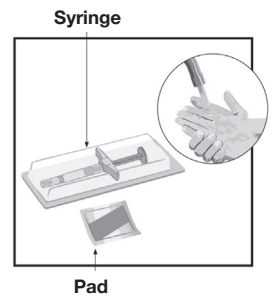
Do not use the pre-filled syringe and call your doctor or pharmacist if the
- liquid is cloudy, discoloured, or has flakes or particles in it
- expiry (EXP) date has passed
- liquid has been frozen or left in direct sunlight
- pre-filled syringe has been dropped or crushed

Do not remove the needle cover until just before injection. Keep Humira out of the sight and reach of children.

STEP 1
Take Humira out of the refrigerator.
Leave Humira at room temperature for **15 to 30 minutes** before injecting.
- **Do not** remove the needle cover while allowing Humira to reach room temperature
- **Do not** warm Humira in any other way. For example, **do not** warm it in a microwave or in hot water

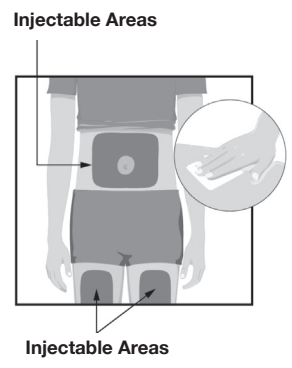
STEP 2
Check expiry (EXP) date. **Do not** use the pre-filled syringe if expiry (EXP) date has passed.
Place the following on a clean, flat surface
- 1 single-use pre-filled syringe
- 1 alcohol pad

Wash and dry your hands.



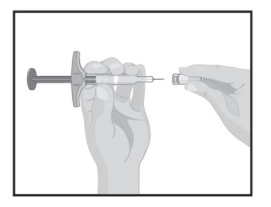
STEP 3
Choose an injection site:
- On the front of your thighs or
- Your belly (abdomen) at least 5 cm from your belly button (navel)
- At least 3 cm from your last injection site

Wipe the injection site in a circular motion with the alcohol pad.
- **Do not** inject through clothes
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, has stretch marks, or areas with psoriasis plaques



STEP 4
Hold the pre-filled syringe in one hand.
Check the liquid in the pre-filled syringe.
- Make sure the liquid is clear and colourless
- **Do not** use the pre-filled syringe if the liquid is cloudy or has particles
- **Do not** use the pre-filled syringe if it has been dropped or crushed

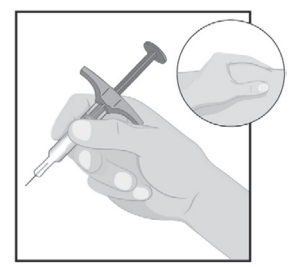
Gently pull the needle cover straight off with the other hand. Throw the needle cover away. Do not recap.
- **Do not** touch the needle with your fingers or let the needle touch anything



STEP 5
Hold the pre-filled syringe with the needle facing up.
- Hold the pre-filled syringe at eye level with one hand so you can see the air in the pre-filled syringe

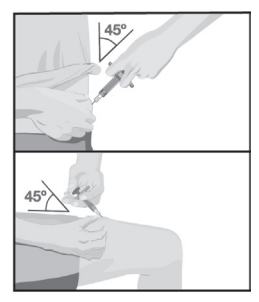
Slowly push the plunger in to push the air out through the needle.
- It is normal to see a drop of liquid at the end of the needle

STEP 6
Hold the body of the pre-filled syringe in one hand between the thumb and index fingers, like you would a pencil.
Squeeze the skin at your injection site with your other hand to make a raised area and hold it firmly.

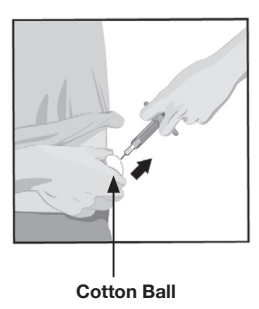


STEP 7
Insert the needle all the way into the skin at about a 45-degree angle with one quick, short motion.
- After the needle is in, let go of the skin you are holding

Slowly push the plunger all the way in until all of the liquid is injected and the pre-filled syringe is empty.



STEP 8
When the injection is completed, slowly pull the needle out of the skin while keeping the pre-filled syringe at the same angle.
After completing the injection, place a cotton ball or gauze pad on the skin over the injection site.
- **Do not** rub
- Slight bleeding at the injection site is normal



STEP 9
Throw away the used pre-filled syringe in a special disposal container as instructed by your doctor, nurse or pharmacist.
Never recap a needle.
- **Do not** recycle or throw the pre-filled syringe in the household waste
- **Always** keep the pre-filled syringe and the special disposal container out of the sight and reach of children

The needle cover, alcohol pad, cotton ball or gauze pad, blister and packaging may be put in your household waste.