Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
The medicine is dispensed according to a doctor's prescription only

AMGEVITA® 100 mg/mL, solution for subcutaneous injection

Adalimumab 100 mg/mL

Amgevita 100 mg/mL - 20 mg solution for injection in pre-filled syringe
Each single dose pre-filled syringe contains 20 mg of adalimumab in 0.2 mL (100 mg/mL) solution.

Amgevita 100 mg/mL - 40 mg solution for injection in pre-filled syringe
Each single dose pre-filled syringe contains 40 mg of adalimumab in 0.4 mL (100 mg/mL) solution.

For inactive ingredients and allergens in the product - see section 6 "Additional Information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

In addition to the leaflet, **Amgevita 100 mg/mL** has a 'Patient safety information card'. This card includes important safety information, which you should know before starting and during the treatment with **Amgevita 100 mg/mL** 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.

Amgevita 100 mg/mL is a biosimilar medicinal product. For further information regarding biosimilar products refer to the Israeli ministry of health website: https://www.gov.il/he/Departments/General/biosimilar

1. What is the medicine intended for?

Rheumatoid arthritis
Amgevita 100 mg/mL 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.

Amgevita 100 mg/mL can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.
Amgevita 100 mg/mL 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

Amgevita 100 mg/mL 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).

Amgevita 100 mg/mL can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Amgevita 100 mg/mL has not been studied in patients aged less than 2 years.

Enthesitis-related arthritis

Amgevita 100 mg/mL 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

Amgevita 100 mg/mL 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

Amgevita 100 mg/mL 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

Amgevita 100 mg/mL 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. **Amgevita 100 mg/mL** 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

Amgevita 100 mg/mL is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who are candidates for systemic therapy.

Pediatric plaque psoriasis

Amgevita 100 mg/mL 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 (HS)

Amgevita 100 mg/mL 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

Amgevita 100 mg/mL 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.

Amgevita 100 mg/mL 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.

Pediatric Crohn's disease
Amgevita 100 mg/mL is indicated for the treatment of moderately to severely active Crohn's disease in pediatric 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
Amgevita 100 mg/mL 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.

Pediatric ulcerative colitis
Amgevita 100 mg/mL is indicated for the treatment of moderately to severely active ulcerative colitis in pediatric 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
Amgevita 100 mg/mL 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.

Pediatric uveitis
Amgevita 100 mg/mL is indicated for the treatment of chronic non-infectious uveitis in pediatric 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
Amgevita 100 mg/mL is indicated for the treatment of intestinal Behcet's disease in patients who have had an inadequate response to conventional therapy.

Therapeutic group: Immunosuppressants, Tumor Necrosis Factor alpha (TNFα) inhibitors.

The active ingredient in **Amgevita 100 mg/mL**, 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 (TNFα), which is involved in the immune (defence) system and is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, **Amgevita 100 mg/mL** 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 "Additional Information").
- You have active tuberculosis or other severe infections (see "Special warnings regarding the 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 the use of the medicine").

Special warnings regarding the use of the medicine

Talk to your doctor or pharmacist before treatment with **Amgevita 100 mg/mL**.

Allergic reactions

- If you get allergic reactions with symptoms such as chest tightness, wheezing, dizziness, swelling or rash, do not inject more **Amgevita 100 mg/mL**, 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 **Amgevita 100 mg/mL**. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL**. You and your doctor should pay special attention to signs of infection while you are being treated with **Amgevita 100 mg/mL**. 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 **Amgevita 100 mg/mL**.
    - As cases of tuberculosis have been reported in patients treated with **Amgevita 100 mg/mL**, your doctor will check you for signs and symptoms of tuberculosis before starting **Amgevita 100 mg/mL**. 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 with **Amgevita 100 mg/mL**, 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 therapy with **Amgevita 100 mg/mL**, 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, **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL**. Your doctor may recommend temporary discontinuation of **Amgevita 100 mg/mL**.

Demyelinating diseases

- 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 **Amgevita 100 mg/mL**. 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.

Vaccines

- Certain vaccines may cause infections and should not be given while receiving **Amgevita 100 mg/mL**.
    - Check with your doctor before you receive any vaccine.
    - It is recommended that children, if possible, be given all the scheduled vaccinations for their age before they start treatment with **Amgevita 100 mg/mL**.
    - If you received **Amgevita 100 mg/mL** while you were pregnant, your baby may be at 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 **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL**, 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 **Amgevita 100 mg/mL**.

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, call your doctor right away.

Cancer

- There have been very rare cases of certain kinds of cancer in children and adult patients taking **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL**, 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 **Amgevita 100 mg/mL**. Some of those patients were also treated with azathioprine or 6-mercaptopurine.
    - Tell your doctor if you are taking azathioprine or 6-mercaptopurine with **Amgevita 100 mg/mL**.
    - Cases of non-melanoma skin cancer have been observed in patients taking **Amgevita 100 mg/mL**.
    - If new skin lesions appear during or after therapy with **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL** could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Children and adolescents
Vaccinations: if possible, children should be up to date with all vaccinations before using **Amgevita 100 mg/mL**.

Other medicines and Amgevita 100 mg/mL
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 **Amgevita 100 mg/mL** 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.

Amgevita 100 mg/mL 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, please ask your doctor.

Pregnancy and breast-feeding
- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last **Amgevita 100 mg/mL** 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.
- **Amgevita 100 mg/mL** 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 **Amgevita 100 mg/mL** during pregnancy compared with mothers with the same disease who did not receive **Amgevita 100 mg/mL**.
- **Amgevita 100 mg/mL** can be used during breast-feeding.
- If you received **Amgevita 100 mg/mL** 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 in the clinic and in the Family Health Center (Tipat-Halav) about your **Amgevita 100 mg/mL** use during your pregnancy before the baby receives any vaccine. For

more information on vaccines see the “Special warnings regarding the use of the medicine” section.

Driving and using machines
Amgevita 100 mg/mL may have a small effect on your ability to drive, cycle or use machines. After treatment with **Amgevita 100 mg/mL**, dizziness and vision disturbances may occur.

Important information about some ingredients of the medicine
Amgevita 100 mg/mL contains sodium
This medicine contains less than 1 mmol of sodium (23 mg) per 0.8 mL dose, i.e. essentially ‘sodium-free’.

Amgevita 100 mg/mL contains polysorbate
Amgevita 100 mg/mL-20 mg: This medicinal product contains 0.2 mg of polysorbate 80 in each 20 mg dose.
Amgevita 100 mg/mL-40 mg: This medicinal product contains 0.4 mg of polysorbate 80 in each 40 mg dose.
Polysorbates may cause allergic reactions. Tell the doctor if you or your child have any known allergies.

3. How to use Amgevita 100 mg/mL

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 and route of administration
Amgevita 100 mg/mL is administered using a syringe by injection under the skin (by subcutaneous injection).
Detailed instructions on how to inject **Amgevita 100 mg/mL** are provided under ‘Instructions for use’.

If you accidentally have taken a higher dosage
If you accidentally inject **Amgevita 100 mg/mL** more frequently than told to 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 Amgevita 100 mg/mL
If you forgot to inject **Amgevita 100 mg/mL**, 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 Amgevita 100 mg/mL
The decision to stop using **Amgevita 100 mg/mL** should be discussed with your doctor.
Your symptoms may return if you stop using **Amgevita 100 mg/mL**.

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 on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

As with any medicine, use of **Amgevita 100 mg/mL** 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 may be serious and require treatment. Side effects may occur at least up to 4 months after the last **Amgevita 100 mg/mL** 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 doesn't heal
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding and paleness

The symptoms described above can be signs of the below listed side effects which have been observed during treatment with **Amgevita 100 mg/mL**.

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;
- edema (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);
- vasculitis (inflammation of blood vessels);
- 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);
- pleural effusion (abnormal collection of fluid in the pleural space);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial edema (swelling of the face);
- gallbladder inflammation, gallbladder stones;
- fatty liver;
- night sweats;
- scar;
- abnormal muscle breakdown;
- 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);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash);
- facial edema (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 (frequency cannot be estimated from the available data):
- 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 medicine 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 platelets count.

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

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "reporting of side effects due to medical treatment" located on the Ministry of Health homepage (**www.health.gov.il**) which directs you to the online form for reporting side effects, or by entering the link: **https://sideeffects.health.gov.il**

5. How to store the medicine

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Store in the original carton in order to protect from light.

A single **Amgevita 100 mg/mL** pre-filled syringe may be stored at temperatures up to a maximum of 25°C for a period of up to 14 days. The pre-filled syringe must be protected from light and discarded if not used within the 14-day period.

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. Additional information

In addition to the active ingredient the medicine also contains: L-lactic acid, sucrose, polysorbate 80, sodium hydroxide and water for injection.

What does the medicine look like and what is the content of the package?
Amgevita 100 mg/mL is a clear and colorless to slightly yellow solution.

Each pack contains 1, 2 or 6 single use pre-filled syringes.

Not all pack types may be marketed.

Manufacturer: Amgen Europe B.V., Minervum 7061, Breda, The Netherlands.

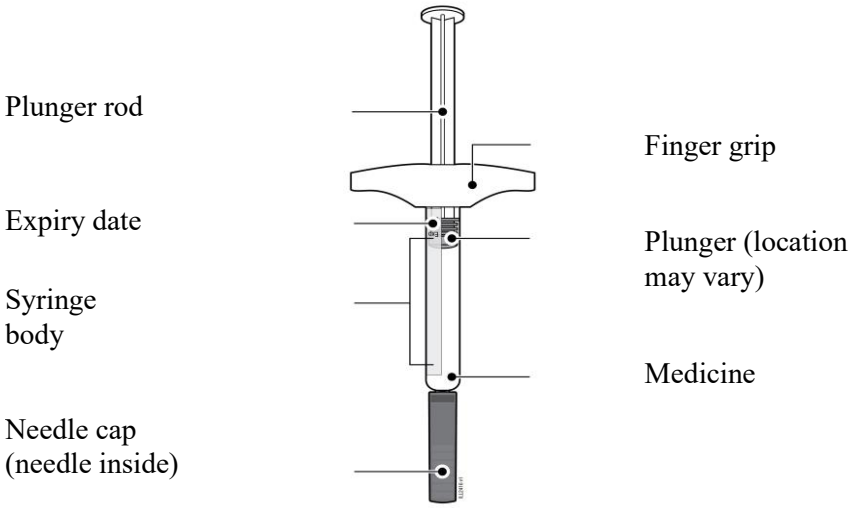
License Holder: Amgen Europe B.V., P.O. BOX 53313, Tel - Aviv, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 179-87-38162-00

Revised in January 2026.

INSTRUCTIONS FOR USE

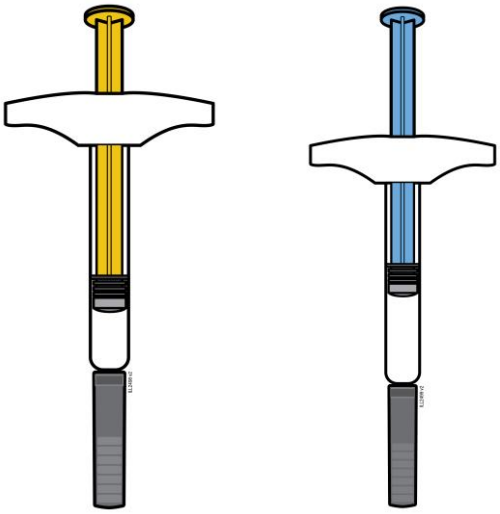
Getting to know your pre-filled syringe



1	**Important information you need to know before injecting AMGEVITA 100 mg/mL**

Dosing:

- **AMGEVITA 100 mg/mL** comes in two different doses: 20 mg/0.2 mL, 40 mg/0.4 mL. Check your prescription to make sure you have the correct dose.
- The color and look of the pre-filled syringe will be different for each dose. The amount of medicine in the pre-filled syringe will also be different for each dose.
- For example, it`s okay for the 20 mg/0.2 mL dose to have a small amount of medicine and the 40 mg/0.4 mL to have a large amount of medicine. Check the illustrations below to see what your dose looks like in the pre-filled syringe.



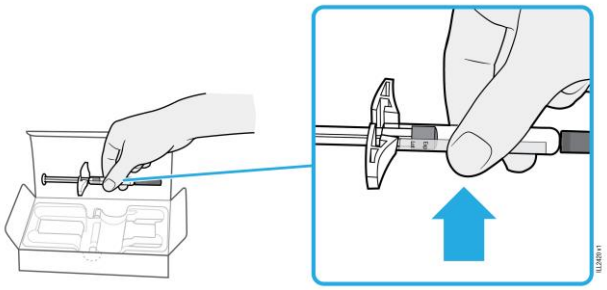
20 mg/0.2 mL **40 mg/0.4 mL**

Using your AMGEVITA 100 mg/mL pre-filled syringe:

- It is important that you do not try to give yourself the injection until you have fully read and understood these instructions for use and unless you have received training from your doctor or healthcare provider.
- **Do not** use the pre-filled syringe if the carton is damaged or seal is broken.
- **Do not** use the pre-filled syringe after the expiry date on the label.
- **Do not** shake the pre-filled syringe.
- **Do not** remove the needle cap from the pre-filled syringe until you are ready to inject.
- **Do not** use the pre-filled syringe if it has been frozen.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Part of the pre-filled syringe may be broken even if you cannot see the break. Use a new pre-filled syringe and call your doctor or healthcare provider.
- The pre-filled syringe is not made with natural rubber latex.

Important: Keep the pre-filled syringe and sharps disposal container out of the sight and reach of children.

2	**Preparing to inject AMGEVITA 100 mg/mL**
2a	**Grasp pre-filled syringe by the body and remove from the carton.**



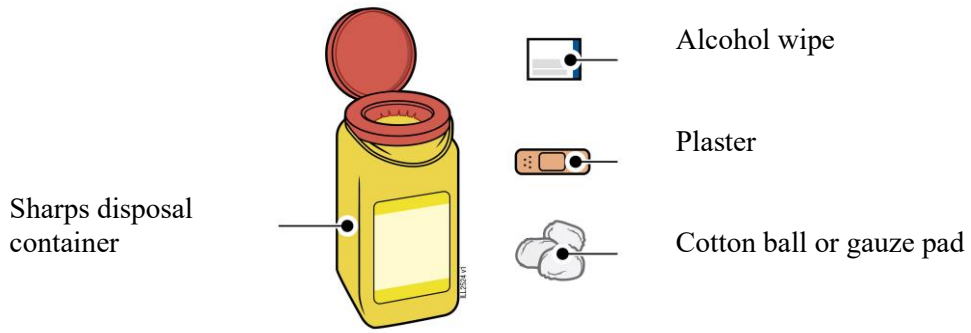
- **Do not** grab the finger grip, plunger rod, or the needle cap.
- Remove the number of pre-filled syringes you need for your injection.
- Put any unused pre-filled syringes back into the refrigerator.

2b	**Wait 30 minutes for the pre-filled syringe to reach room temperature.**

WAIT
30
minutes

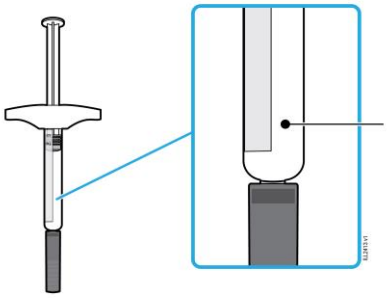
- Let the pre-filled syringe warm up naturally.
- **Do not** heat with hot water, a microwave, or direct sunlight.
- **Do not** shake the pre-filled syringe at any time.
- **Do not** place pre-filled syringe back in refrigerator after it has reached room temperature.
- Using the pre-filled syringe at room temperature allows for a more comfortable injection.

2c	**Gather and place the items for your injection on a clean, well-lit surface.**



- **AMGEVITA 100 mg/mL** pre-filled syringe (room temperature)
- Sharps disposal container
- Alcohol wipe
- Plaster
- Cotton ball or gauze pad

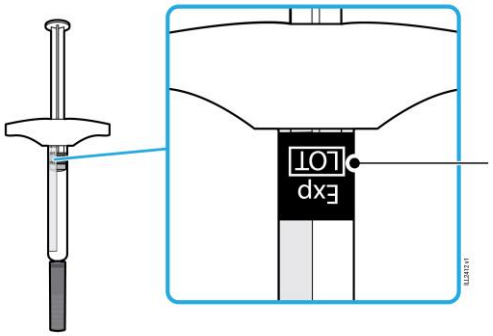
3	**Getting ready for your injection**
3a	**Inspect the medicine.**



- It should be clear and colorless to slightly yellow.
- It is okay to see air bubbles in the pre-filled syringe.
- **Do not** use if the medicine is cloudy, discolored, or contains flakes, or particles.

Important: If the medicine is cloudy, discolored, or contains flakes or particles, call your doctor or healthcare provider.

3b	**Check the expiry date (EXP) and inspect the pre-filled syringe for damage.**

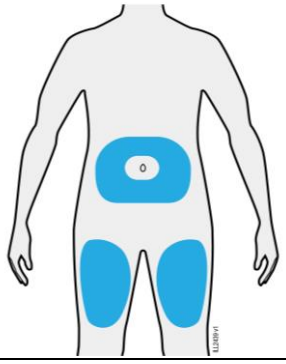


Expiry date

- **Do not** use if the expiry date has passed.
- **Do not** use the pre-filled syringe if:
  - The needle cap is missing or not securely attached.
  - It has cracks or broken parts.
  - It has been dropped on a hard surface.

Important: If the pre-filled syringe is medicine is damaged or expired, call your doctor or healthcare provider.

3c	**Inject in one of these locations.**

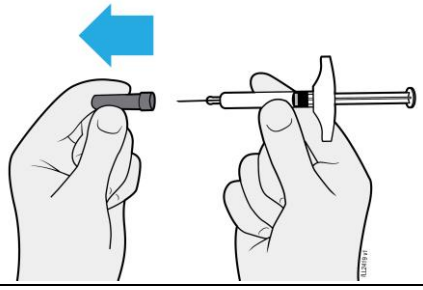


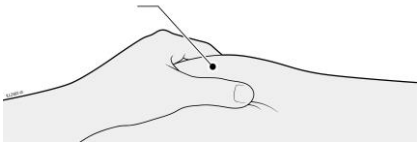
- Inject in your thigh or belly (except 5 cm around your belly button).
- Choose a different site for each injection.
- Wash your hands thoroughly with soap and water.
- Clean injection site with an alcohol wipe.
- Let your skin dry on its own.
- **Do not** touch this area again before injecting.

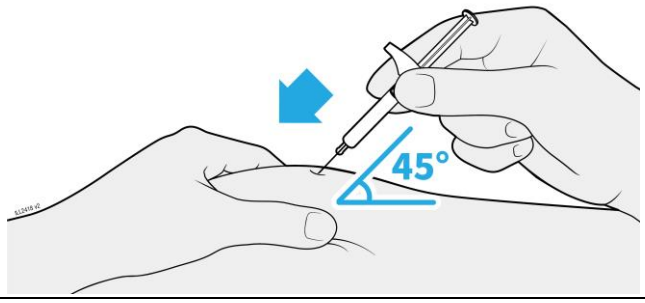
Important: Avoid areas with scars, stretch marks, or where skin is tender, bruised, red or hard.

4	**Injecting AMGEVITA 100 mg/mL**

Important: Only remove the needle cap when you can inject right away (within 5 minutes) because the medicine can dry out.

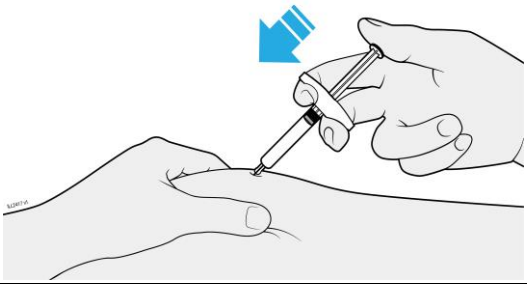
4a	**Pull the needle cap straight off while holding the pre-filled syringe barrel.**
	
• **Do not** twist or bend the needle cap. • **Never** put the needle cap back on. It may damage the needle. • **Do not** let anything touch the needle once the needle cap is removed. • **Do not** place the uncapped pre-filled syringe on any surface once the needle cap is removed. • **Do not** try to push air bubbles out of the pre-filled syringe. It is okay to see air bubbles. • A drop of medicine is normal.	

4b	**Pinch the skin around the injection site before the injection.**
PINCH **skin at injection site** 	
• Pinch the skin between thumb and index finger to create a bump for the injection. • If possible, the bump should be about 5 cm wide.	

4c	**Insert the needle into the pinched skin.**
INSERT 	
• Insert the needle into the pinched skin either straight in or at a 45 degree angle. • **Do not** place your finger on the plunger rod while inserting the needle, as this may result in loss of medicine.	

4d	**Slowly press the plunger rod down to the bottom of the pre-filled syringe to inject the medicine.**

INJECT



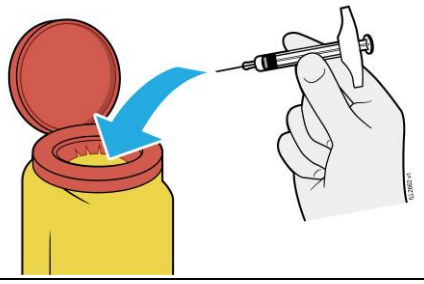
- **Do not** pull back on the plunger at any time.
- **Do not** remove the needle until all the medicine is delivered.

Important: Continue to pinch the skin until injection is complete.

5	**Disposing and finishing AMGEVITA 100 mg/mL**

Important: Never put the needle cap back on.

5a	**Discard the used pre-filled syringe and needle cap in the sharps disposal container.**



Do not recycle the pre-filled syringe or throw it into the household waste.

- **Do not** re-use the pre-filled syringe.
- **Do not** use any medicine that is left in the used pre-filled syringe.
- Put the used **AMGEVITA 100 mg/mL** syringe in a sharps disposal container immediately after use.
  Do not throw away (dispose of) the syringe in your household waste.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- **Do not** recycle the syringe or sharps disposal container or throw them into the household waste.

Important: Always keep the sharps disposal container out of the sight and reach of children.

5b	**Check injection site.**

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply a plaster if necessary.