

AMGEN



Stock photo. Shown with a model

# My therapy guidebook

Information about  
therapy with AMGEVITA<sup>®</sup>

# Contents

What happens in a chronic inflammatory disease?.....	6
Adalimumab: For the treatment of chronic inflammatory diseases.....	8
AMGEVITA®. An adalimumab biosimilar. ....	10
How well is treatment with AMGEVITA® tolerated?.....	12
Important information before using AMGEVITA®. ....	14
How to correctly use AMGEVITA®. ....	16
How to properly store AMGEVITA®. ....	24
Patient support from the start. ....	26
Glossary .....	28



Stock photo. Shown with a model

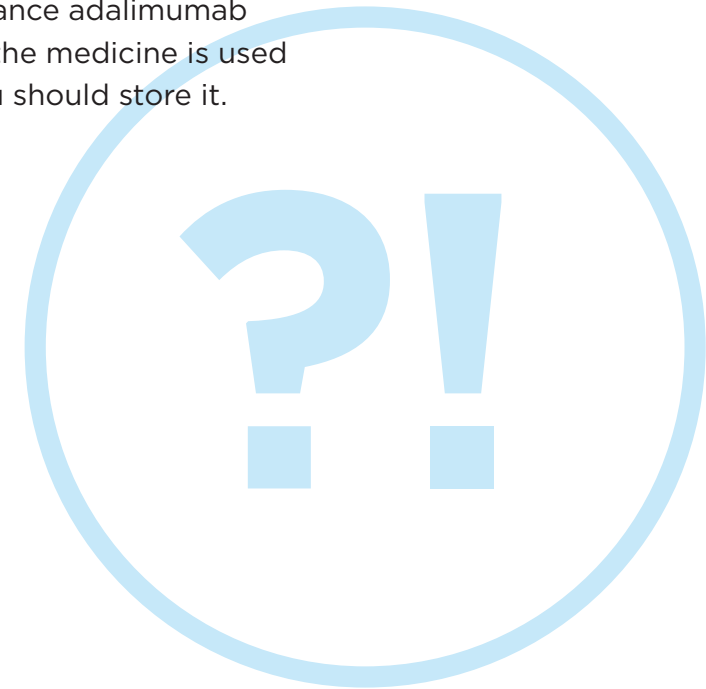
## Dear Reader,

Your doctor has prescribed therapy with AMGEVITA® to you. The medicine with its active substance adalimumab is used for the targeted treatment and relief of symptoms in chronic inflammatory diseases such as rheumatoid arthritis, psoriasis and Crohn's disease.

With this booklet, we want to show you what a chronic inflammatory disease is, how the active substance adalimumab works, how the medicine is used and how you should store it.

Read the individual chapters at your own pace and also use the booklet later as a reference guide.

Your attending doctor is of course still the most important contact partner for any questions. You will find all of the important information on AMGEVITA® in the package leaflet located in the box of your medicine.



# What happens in a chronic inflammatory disease?



## **Inflammation - normally an essential protective reaction.**

If the immune system identifies damaged body cells or invaders in the body, it combats them. This can be triggered by disease pathogens or mechanical damage, but also heat, cold, or nicotine. The defence reaction manifests in the form of inflammation. When the invaders or damaged body cells are destroyed or broken down, the defence reaction ends and the inflammation subsides.

## **Chronic inflammatory disease.**

In a chronic inflammatory disease, this natural defence reaction no longer ends. The immune system now also acts against the body's own healthy tissue. Chronic inflammation develops and does not subside.

## **Treatment options.**

To decrease the inflammatory activity, relieve pain and increase patients' well-being, various active substances are used, depending on the disease. The combination of known and new basic therapeutic drugs as well as biotechnologically produced medicines (biologics) have expanded the therapeutic options.

## **The role of messengers.**

The body uses various messengers (cytokines) to control the immune system's defence reaction. There are messengers that initiate inflammation, those that maintain inflammation, and those that allow inflammation to subside. The messenger TNF-alpha is one of the most important inflammation-maintaining messengers in the immune system. This is where the active substance adalimumab comes into play - by binding to this messenger and thus blocking it. It is therefore also referred to as TNF-alpha blocker.

# Adalimumab: For the treatment of chronic inflammatory diseases.<sup>1</sup>

## What is adalimumab?

Adalimumab is a biologic prescribed for the treatment of chronic inflammatory diseases, such as rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease and ulcerative colitis.

## What makes up a biologic such as adalimumab?

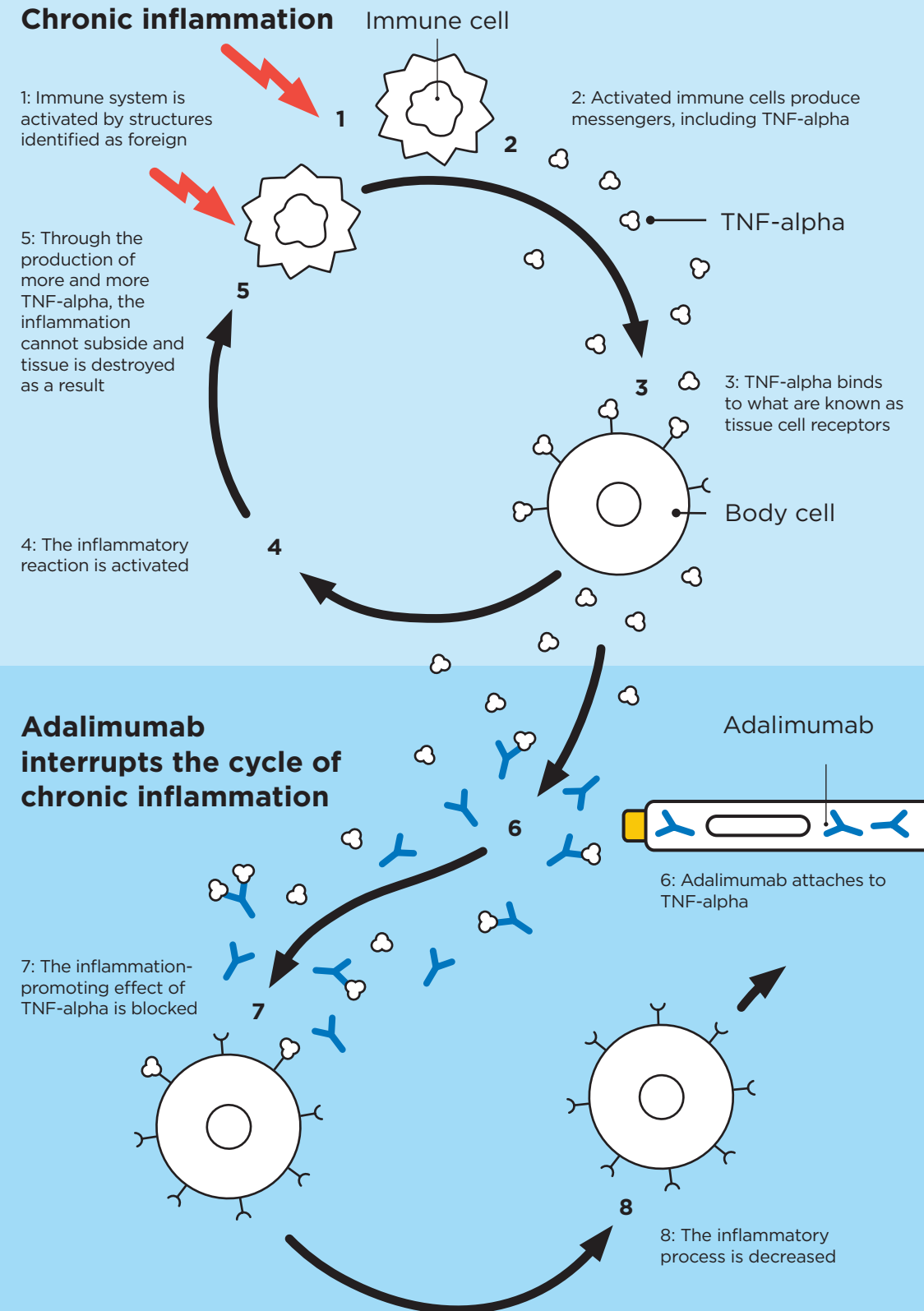
Biologics are complex medicines that are produced in living cells and that are specifically targeted against disease-causing structures. The target structure of adalimumab is a special - inflammation-causing - messenger of the immune system that is to be blocked.

## How does adalimumab work?

The active substance of AMGEVITA®, adalimumab, is a human monoclonal antibody. Monoclonal antibodies are proteins that attach to a particular target. The target of adalimumab is the protein tumour necrosis factor alpha (TNF-alpha). TNF-alpha is involved in the body's defence reactions. In the above-mentioned diseases, the amount of TNF-alpha is increased.

AMGEVITA® attaches to TNF-alpha, blocks it and thus decreases the inflammatory processes of these diseases.<sup>1</sup>

<sup>1</sup> AMGEVITA® is approved for the treatment of rheumatoid arthritis in adults, juvenile idiopathic arthritis in adults, children and adolescents, axial spondyloarthritis with and without radiological evidence of ankylosing spondylitis in adults, psoriasis in adults, psoriatic arthritis in adults, plaque psoriasis in children and adolescents, hidradenitis suppurativa/acne inversa in adults and adolescents, Crohn's disease in adults, children and adolescents, ulcerative colitis in adults, as well as uveitis in adults, children and adolescents.



# AMGEVITA®.

## An adalimumab biosimilar.



Stock photo. Shown with a model

### What is a biosimilar?

A biosimilar is a biotechnologically produced medicinal product (biologic). It is structurally very similar to the original medicinal product (reference product) and corresponds to it in terms of effect and safety. The development and production of biosimilars is similarly complex as that of the reference products.

### Mode of action confirmed in studies.

AMGEVITA® has been investigated worldwide in various studies on thousands of patients. The study results showed that your medicinal product is just as effective and well tolerated as the adalimumab original medicinal product.

---

**AMGEVITA® is a medicinal product to decrease the inflammatory process. It is used to treat the following diseases:**

#### Inflammatory rheumatic diseases

- Rheumatoid arthritis in adults
- Juvenile idiopathic arthritis in adults, children and adolescents
  - Polyarticular juvenile idiopathic arthritis in ages 2 and up
  - Enthesitis-associated arthritis in ages 6 and up
- Axial spondyloarthritis in adults
  - Ankylosing spondylitis (AS)
  - Axial spondyloarthritis without evidence on X-ray of AS
- Psoriatic arthritis in adults

#### Chronic inflammatory skin diseases

- Plaque psoriasis in adults, children and adolescents aged 4 and up
- Hidradenitis suppurativa (acne inversa) in adults and adolescents aged 12 and up

#### Chronic inflammatory intestinal diseases

- Crohn's disease in adults, children and adolescents aged 6 and up
- Ulcerative colitis in adults and children aged 6 and up

#### Chronic inflammatory eye diseases

- Uveitis in adults, children and adolescents aged 2 and up



## How well is treatment with AMGEVITA® tolerated?

Like all medicines, this medicine may have side effects, however not everyone gets them. Most of the side effects are mild to moderate. However, some may also be serious and need to be treated. Side effects may occur at least up to four months after the last injection of AMGEVITA®.

Important information on treatment with your medicine and possible side effects can be found in the package leaflet located in the box of your medicine.

During your treatment, you should:

- Tell your doctor how the medicine is working for you.
- Call your doctor immediately if you experience any side effects.

If a side effect develops, your doctor will decide whether you should continue to receive AMGEVITA®.

Information on reporting side effects can be found in the information below.

**Tell your doctor about all new symptoms that you experience, new medicines you are taking (including prescription and non-prescription medicines, vaccinations, vitamins and nutritional supplements), and all surgical procedures, dental treatments or operations.**

---

If you notice side effects, contact your **doctor, pharmacist, or a medical professional**. This also applies to side effects that are not listed in the package leaflet.

You can also directly report side effects to the **Federal Institute for Vaccines and Biomedicines**, Paul-Ehrlich-Institut  
Paul-Ehrlich-Str. 51-59, 63225 Langen  
Tel.: +49 (0)6103 77 0, Fax: +49 (0)6103 77 1234  
Internet: [www.pei.de](http://www.pei.de)

Side effects can also be reported to **Amgen GmbH**, Department of Drug Safety:  
Tel.: 0800 264 36 58, email: [eudemicalsafety@amgen.com](mailto:eudemicalsafety@amgen.com)

# Important information before using AMGEVITA®.



Stock photo. Shown with a model

## **Intended only for you.**

This medicine was prescribed to you personally. Do not give it to anyone else. It can harm other people, even if they have the same symptoms as you.

## **You must not use AMGEVITA® if you:**

- are allergic to the active substance adalimumab or one of the other ingredients of this medicine,
- are suffering from active tuberculosis or another serious infection,
- are suffering from moderate to severe heart failure.

Tell your doctor if you have signs of an infection, such as fever, wounds, fatigue or dental problems and inform him or her of any previous or current serious heart problems.

**A detailed list of warnings and precautionary measures can be found in the package leaflet enclosed with AMGEVITA®.**

## **Always keep the patient card with you.**

In addition to this booklet, your doctor also gave you a patient card that contains important safety information. Always keep this patient card with you. If you have further questions, contact your doctor or pharmacist.



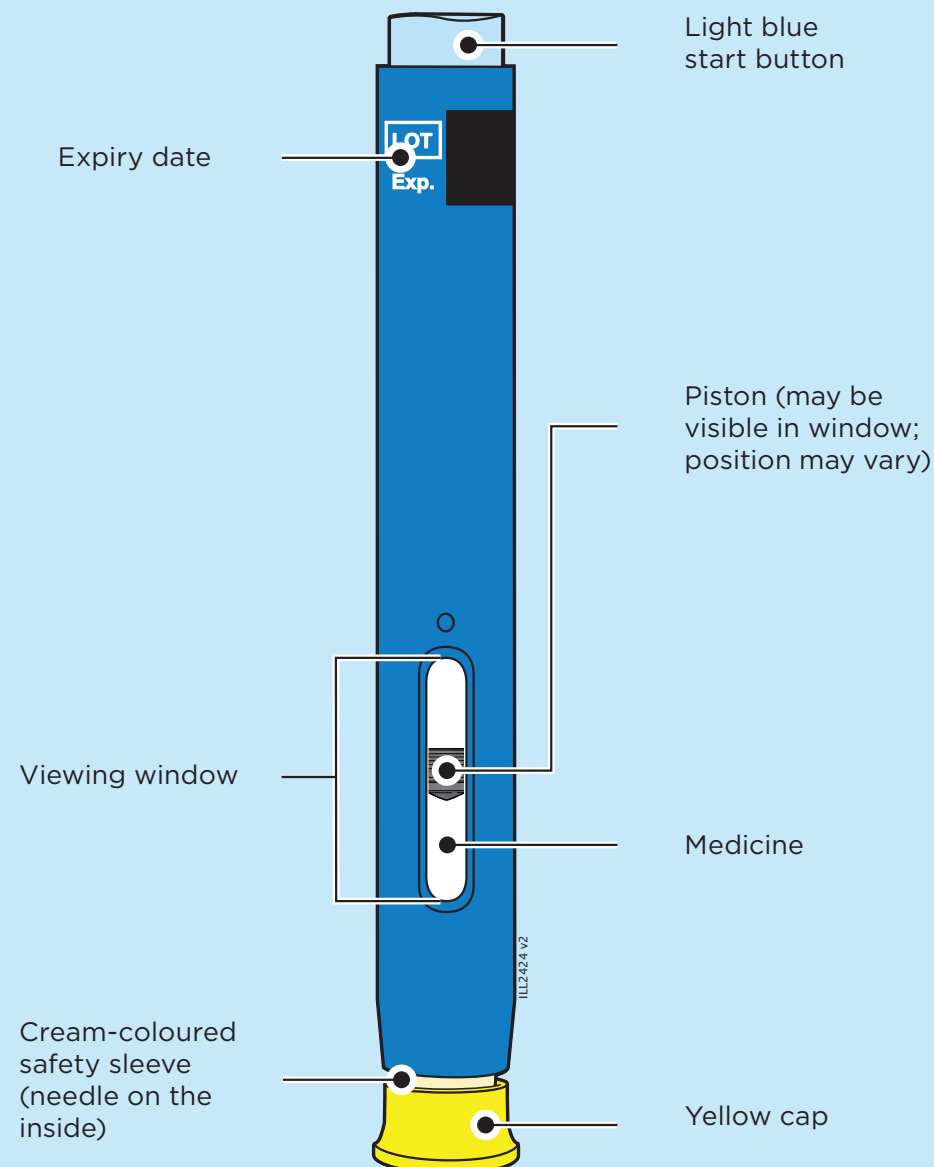
# How to correctly use AMGEVITA®.

Your first injection with your medicine is carried out under the supervision of a trained medical professional. AMGEVITA® is used with the SureClick® pre-filled pen - an application aid for single use. In addition to the SureClick® pre-filled pen, AMGEVITA® is also available in a pre-filled syringe.

**On the right is a brief introduction to self-injection. Detailed instructions can be found in the package leaflet supplied with your medicine. If you are not sure, contact your doctor or a medical professional.**

## Read this important information before you use an AMGEVITA® pre-filled pen:

- It is important that you do not attempt to give yourself an injection before you have fully read and understood these instructions and been trained by your doctor or a medical professional.
- Do not use an AMGEVITA® pre-filled pen if it fell onto a hard surface. Parts of the AMGEVITA® pre-filled pen can be damaged, even if you cannot identify any damage. Use a new AMGEVITA® pre-filled pen.



## Step 1

### Take an AMGEVITA® pre-filled pen out of the packaging.

Carefully lift the pre-filled pen straight out of the box 30 minutes before the injection so that it can come to room temperature. Put the original packaging with the unused AMGEVITA® pre-filled pens back in the refrigerator.

#### Never:

- put the pre-filled pen back into the refrigerator once it has reached room temperature
- attempt to warm the pre-filled pen by using a source of heat such as hot water or a microwave
- shake the pre-filled pen
- remove the yellow cap from the pre-filled pen already

## Step 2

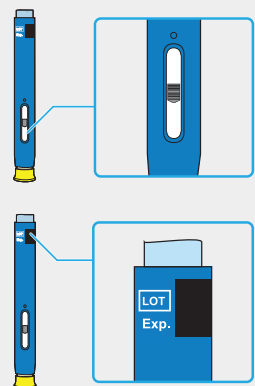
### Check the AMGEVITA® pre-filled pen.

Check the medicine. It should be clear and colourless to slightly yellowish.

Check the expiry date (EXP) and check the pre-filled pen for damage.

#### Do not use the pre-filled pen if:

- the medicine is cloudy or discoloured or contains flakes or particles.
- the pre-filled pen has cracks or broken parts.
- the pre-filled pen fell onto a hard surface.
- the yellow cap is missing or loose.
- the expiry date printed on the label has passed.



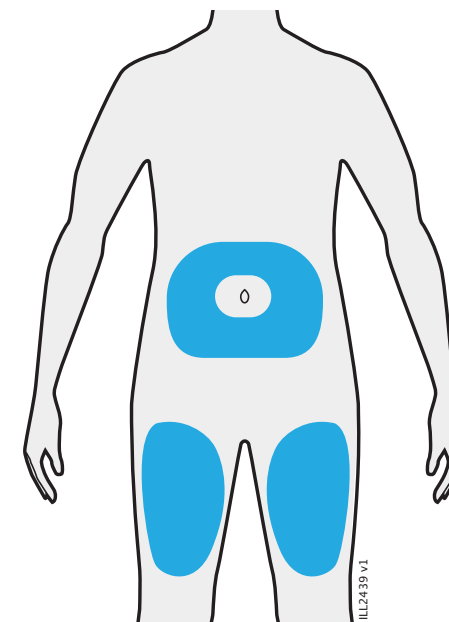
## Step 3

### Prepare the injection site and clean it.

#### Select your injection site:

- **Thigh**  
or
- **Abdomen** (except for the area about 5 centimetres around the navel)

Wash your hands thoroughly with soap and water. Disinfect the injection site with an alcohol wipe. Once the skin is dry, you are ready for the injection.



#### Important:

- Do **not** touch the injection area before the injection.
- Ensure that you are not positioned at exactly the same injection site that you used for a previous injection.
- Do not select any areas where the skin is sensitive, reddened or hardened or where there is bruising - avoid injecting in areas with scars or stretch marks.
- If you suffer from psoriasis, avoid a direct injection into swollen, thick, reddened or flaky areas of skin or lesions.

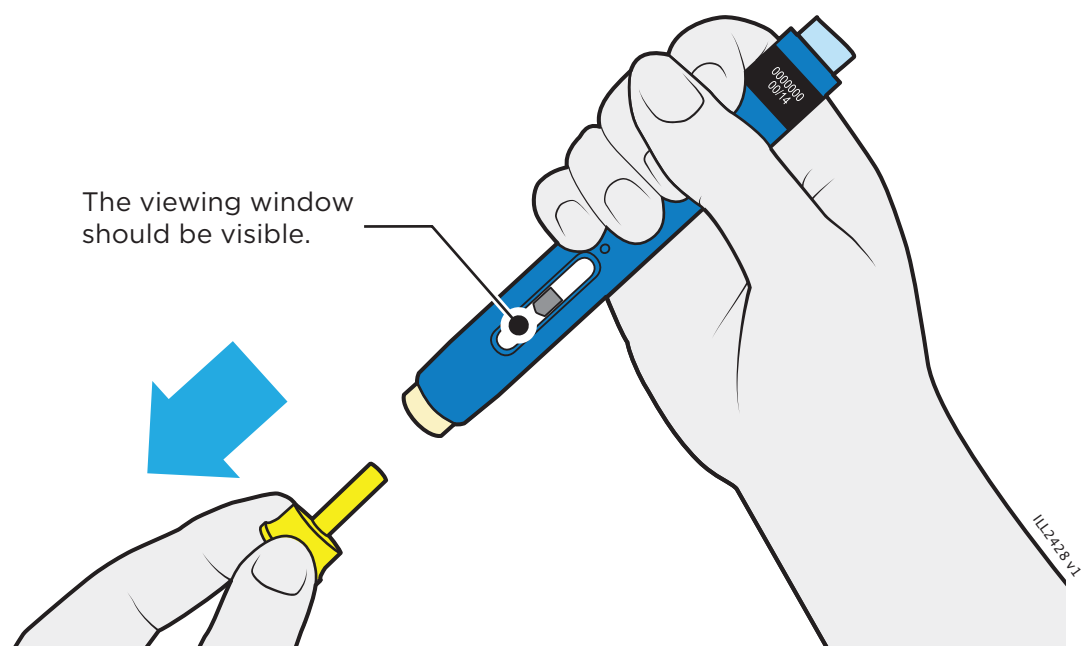
## Step 4

### Remove the yellow cap.

Do not remove the yellow cap until just before (max. 5 minutes) the injection because the medicine can dry out. Hold the pre-filled pen such that you can see the viewing window. Pull the yellow cap straight off. You may need to pull firmly. It is normal to see a drop of medicine at the tip of the needle or the cream-coloured safety sleeve.

#### Never:

- rotate, bend or jiggle the yellow cap
- place the yellow cap back onto the pre-filled pen
- put your finger into the cream-coloured safety sleeve



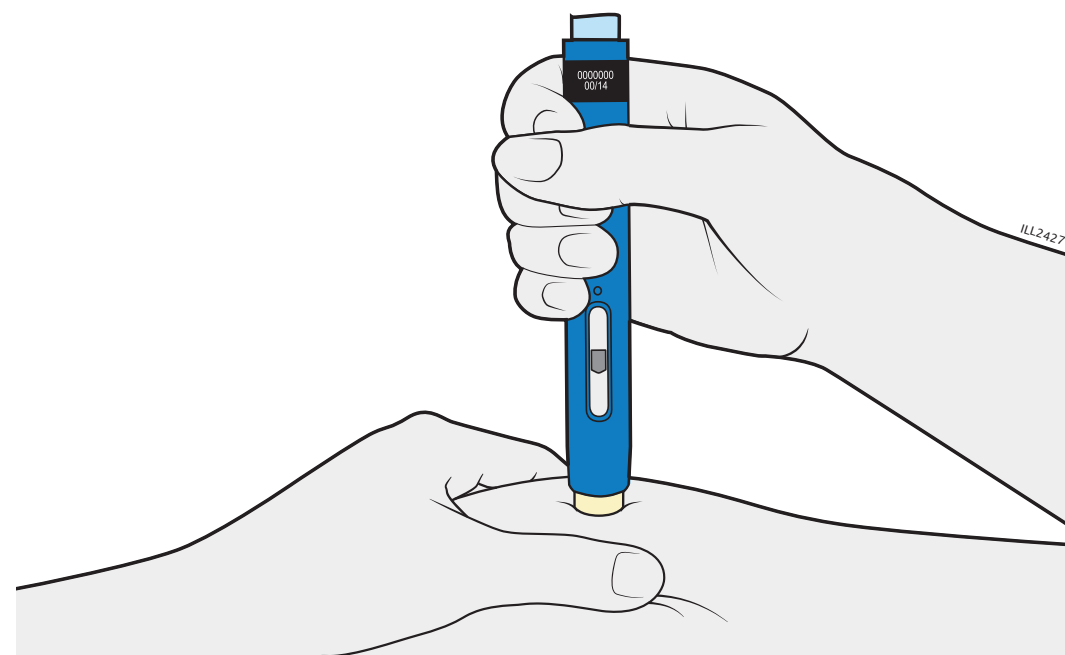
## Step 5

### Create a firm surface for the injection and position the pre-filled pen.

#### Pinch method:

Firmly pinch the skin between your thumb and fingers so that an area about 5 cm wide is created.

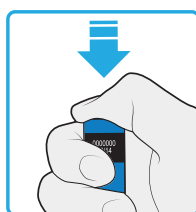
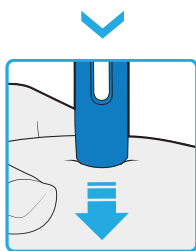
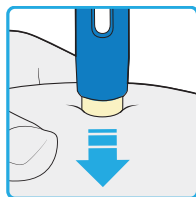
Place the cream-coloured safety sleeve on the skin. Continue to pinch the skin until the injection is completed. Make sure that you can see the viewing window. Ensure that you keep the autoinjector perpendicular (at a 90-degree angle) to the injection site.



## Step 6

### Hold the pre-filled pen in place.

- Press the pre-filled pen firmly against your skin until the cream-coloured safety sleeve does not move any further.
- You have to press all the way down and not release.
- The cream-coloured safety sleeve is pushed in and unlocks the light blue start button.
- Continue to hold the pre-filled pen firmly against the skin and press the light blue start button to start the injection.

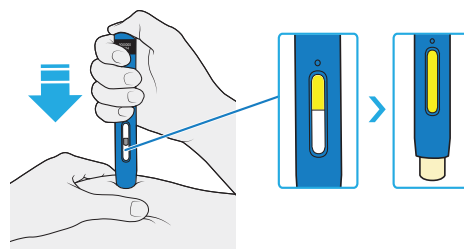


- You may hear or feel a click. The viewing window turns yellow and you may now release the light blue start button.

## Step 7

### Continue to press the pre-filled pen against the skin.

You may hear or feel a click. The viewing window turns yellow when the injection is completed. It may take up to 15 seconds until the injection is completed. You may hear a second click. You may now remove the pre-filled pen from the skin; the cream-coloured safety sleeve encloses the needle.



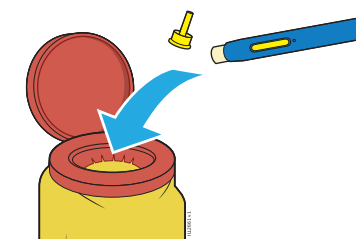
### Important:

If you remove the pre-filled pen from the skin and the viewing window has not turned yellow or if it looks as if the medicine is yet to be injected, it may mean that you did not receive a full dose. Call your doctor or the medical staff immediately.

## Step 9

### After the injection

Dispose of the used pre-filled pen and the yellow cap immediately after use in a puncture-resistant container. Do not dispose of the used pre-filled pen in household waste. Talk to your doctor or pharmacist about proper disposal.



### Important:

Do not reuse the used pre-filled pen and do not touch the cream-coloured safety sleeve. Always store the puncture-resistant container out of the reach of children.

## Step 10

### Check the injection site.

If the injection site is slightly bleeding, press a cotton-wool ball or gauze against it for a few seconds.

**Do not rub** the injection site. If necessary, use a plaster.



## How to properly store AMGEVITA®.

Store AMGEVITA® in the original box in the refrigerator to protect it from light. To safely store your medicine, be aware of the following guidelines:

- Like all medicines, store it out of the reach of children.
- Always leave AMGEVITA® in the protective original box.
- Store the medicine in the refrigerator at 2 to 8°C.
- Do NOT expose AMGEVITA® to extreme heat or cold.
- Do not freeze the medicine.
- Do not expose AMGEVITA® to direct sunlight.

### On the go and when travelling.

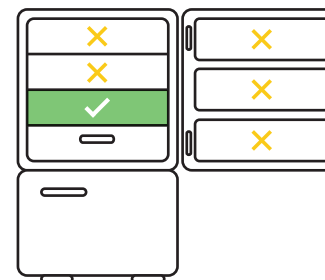
You can store an individual AMGEVITA® pre-filled pen or an individual pre-filled syringe below 25°C and protected from light for up to 14 days.

- Never place the pre-filled pens or pre-filled syringes back into the refrigerator once they have reached room temperature.
- Discard the pre-filled pens or pre-filled syringes if they have been stored for more than 14 days at room temperature.

Special cooler bags are suitable for transport. You can obtain these in your pharmacy, for example, or order them via the AmgenCare service programme. More information about AmgenCare can be found on the next page.

### The best place for storage.

There are colder and warmer zones in your refrigerator. Store your medicine in the middle area of your refrigerator. Here in particular, the temperature is generally consistently between 2 and 8°C.



**Correct:** In the middle area of the refrigerator, the temperature is consistently between 2 and 8°C.

**Too cold:** AMGEVITA® could freeze at the wall of the refrigerator.

**Too warm:** Temperatures greatly fluctuate at the door of the refrigerator.



**Store your medicine in the refrigerator at 2 to 8°C.**



**Always leave AMGEVITA® in the protective original box.**

# Patient support from the start



With AmgenCare, Amgen offers a very **comprehensive and free-of-charge** patient support programme, because chronic diseases are challenging, both psychologically and physically. It is reassuring to know that there are lots of good medicines available and that people with these conditions can also share their questions, concerns and needs. This holistic approach is close to Amgen's heart.

<b>Nutritional advice</b>	<b>Service hotline</b>	<b>Travel</b>
<b>AmgenCare website</b>	<b>Your personal health advice</b>	<b>Information on conditions</b>
<b>Stress management</b>	<b>Information about benefit entitlements</b>	<b>Smoking cessation</b>

These materials and more are available at:  
[www.amgencare.de/servicematerial](http://www.amgencare.de/servicematerial)



What makes AmgenCare so special is that you will have your own personal health advisor and everything is tailored to your needs. AmgenCare provides you with individual support on any questions you might have about managing your condition and using Amgen medication.

You are welcome to try out AmgenCare at no obligation first and then decide whether AmgenCare might be helpful for you.



For references, please scan the QR code or phone 0800 118 81 18 from 8:00 to 20:00.  
**For further information refer to [www.amgencare.de](http://www.amgencare.de)**

Amgen has succeeded in engaging **Sanvartis GmbH**, one of the largest healthcare service providers in Germany, for AmgenCare. This means that Amgen itself does not receive any of your personal data.



**Support at AmgenCare can currently be provided only in German.**

# Glossary

## Adalimumab

This is the name of the active substance of AMGEVITA®. Adalimumab is an *antibody* that binds to the messenger *TNF-alpha*. As a result of the bond, the inflammation-maintaining *TNF-alpha* is blocked.

## Ankylosing spondylitis

See *Bechterew's disease*

## Antibody

*Proteins* that are formed by the *immune system* after the body comes into contact with pathogens. Antibodies bind to substances that are foreign to the body and help render them harmless. In this way, they form an important part of the immune system. Biotechnologically produced antibodies harness this mode of action as a medicinal product.

## Axial spondyloarthritis

A chronic rheumatic inflammatory disease with accompanying inflammation at the spine. If this inflammation is so advanced (and ossified) that it is visible on an X-ray, it is more specifically referred to as *ankylosing spondylitis*, better known as *Bechterew's disease*.

## Bechterew's disease

Synonym: *ankylosing spondylitis*. A *chronic inflammation* of the joints of the spinal column, starting at the sacral region. Over time, there is ossification and stiffness of the spinal column with painful limitations of movement and also respiration.

## Biologic

A substance that originates from or is created by a living organism and that is used for the diagnosis, prophylaxis or treatment of diseases. Simple biologics include, for example, insulin and growth hormones, while *antibodies* are significantly more complex and larger.

## Biosimilar

A biotechnological medicinal product for which a high degree of structural similarity and correspondence with regard to efficacy and safety with an already approved *biologic* (reference product) has been demonstrated.

## Chronic inflammation

Inflammation is an action by the body to rid itself of harmful stimuli and repair resultant tissue damage. Triggers can, for example, be disease pathogens or mechanical damage, heat, cold, or also nicotine. Chronic (that is, lasting) inflammation develops when the harmful stimulus cannot be combated or if the inflammation targets the body's own structures. The inflammation does not subside, but rather can lead to further tissue and consequential damage.

## Crohn's disease

An incurable, relapsing inflammation of the entire gastrointestinal tract, from the oral cavity to the anus. In contrast to *ulcerative colitis*, the proliferation is not continuous, however the entire intestinal wall (and not just the mucosa) is affected, which can lead to fistula formation. The cause is unknown.

## Enthesitis-associated arthritis

A subform of *juvenile idiopathic arthritis*. Joints as well as tendon insertions (generally the Achilles tendon) are affected by the painful inflammation. 75% of the patients are male.

## Hidradenitis suppurativa (Acne inversa)

A chronic inflammation of the hair roots (hair follicles) and sebaceous glands – generally in the armpits or groin and genital region. Recurring painful abscesses and fistulas form.

## Immune system

The body's own defence system to combat disease pathogens, harmful substances or stimuli as well as malfunctioning cells of the body. It includes blood cells, tissues and organs that are involved in the organism's defence against infections and whose function is to preserve the body's own structure by defending against harmful stimuli, substances and disease pathogens. The immune system also includes *antibodies* and *messengers* that are involved in an immune reaction.

## Messengers

Chemical substances in the body that are used for signal transmission and communication between cells of the body. These include, for example, adrenalin or serotonin as well as inflammation-maintaining *TNF-alpha*.

## Polyarticular juvenile idiopathic arthritis (JIA)

Synonym: juvenile chronic arthritis (JCA). A relapsing chronic inflammation of many joints that appears before the age of 16 and has been present for at least 6 weeks. *Enthesitis-associated arthritis*, *rheumatoid arthritis* and *psoriatic arthritis* in childhood in each case fall under this category of joint inflammation.

## Protein

Proteins are made from amino acids and are the building block of every cell. They give structure to the cell and thus to the entire organism and form muscles, hair, skin and the brain, for example. They function as a tool and transport oxygen in the blood (haemoglobin), for example, or initiate chemical reactions. As *antibodies* they are used for defence against infections.

## Psoriasis

Non-contagious chronic inflammatory skin disease with reddened skin and silvery flakes. It has a relapsing course and is incurable. The cause is not fully clarified, however there is a hereditary component. Generally the extensor sides of the arms and legs, the palms and soles of the feet, as well as the back are affected; often also the scalp and sometimes even the joints.

## Psoriatic arthritis

A rheumatic autoimmune disease that in particular attacks the cells of the tendons and joints, as well as of the skin, nails and, rarely, the internal organs through the secretion of inflammation-promoting messengers. It results in lasting inflammation that can cause pain and damage.

## Rheumatoid arthritis

Colloquially: Rheumatism. Painful chronic inflammatory *systemic disease* with increasing destruction of the joints and deformation of the affected limbs to the point of disability. Other organs can also be affected, such as the heart or vessels. The exact causes of this incurable disease are largely unclear. The therapy includes various medicines, physiotherapy and pain-relieving applications.

## Systemic disease

A disease that does not remain limited to a local area, but rather attacks an entire organ system (such as *rheumatoid arthritis*) or affects the entire organism (e.g. diabetes).

## TNF-alpha

A messenger of the *immune system* with many functions: It is involved in inflammation and activates other *messengers*.

## Tuberculosis (TBC)

A notifiable bacterial infectious disease of the lungs, but other organs can also be affected. When the immune status is good, the inhaled bacteria can be "walled in" in a so-called granuloma in the lung following an infection and they are contained as a result. However, years later, in the case of a poor immune status, reactivation is possible.

## Ulcerative colitis

Chronic, continuous inflammation, generally with a relapsing course, exclusively of the rectum and colon. Ulcers form in the intestinal mucosa and painful, bloody-mucous diarrhoea develops. The cause of the disease is largely unknown.

## Uveitis

Inflammation of the middle layer of the eye (the uvea, consisting of the choroid, the iris and the so-called ciliary body, the circular supporting apparatus around the iris in the eye).

**Amgen GmbH**

Riesstraße 24, 80992 Munich

Tel.: (089) 14 90 96-0

Fax: (089) 14 90 96-2000

© 2024 Amgen Inc.

All rights reserved.

**MedInfo hotline**  
**0800 264 36 44**

Medical-scientific product inquiries  
Mon.-Fri. from 8 a.m. to 6 p.m. or  
online at [medinfo.amgen.de](https://medinfo.amgen.de)

