

AMGEN



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Insights into day-to-day therapy

Information about your
treatment with WEZENLA[®]

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Dear patient,

You are receiving WEZENLA^{®1}, a new medicinal product with the active substance ustekinumab which has been developed by Amgen, a leading manufacturer of biopharmaceuticals. This booklet is designed to tell you more about your new treatment and why your doctor has recommended it for you.

Your treatment team will be pleased to answer any questions.



1 What is WEZENLA[®] used for?

WEZENLA[®] is approved for the treatment of various chronic inflammatory conditions:¹



Plaque psoriasis

This is an auto-immune skin disease, also known as psoriasis vulgaris. The name comes from the dry “plaques” or patches covered with silvery or whitish scales which can form on some areas of the body.



Psoriatic arthritis

Psoriatic arthritis is an auto-immune condition that affects the joints and occurs in around a third of people with plaque psoriasis.² It causes inflammation, primarily on the hands and feet on one side of the body. They become swollen, painful and difficult to move.



Crohn's disease

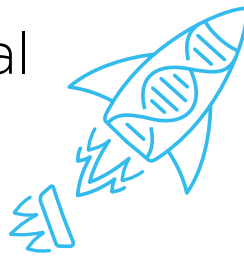
Crohn's disease is another chronic inflammatory condition, which affects the entire digestive tract and all layers of the intestinal wall from the mouth to the rectum. Symptoms include chronic diarrhoea, spasmodic abdominal pain and fever.



2 What kind of active substance is ustekinumab?

Ustekinumab is the active substance in WEZENLA®. It is an antibody that can alleviate the symptoms of your condition and help to stop them deteriorating. The aim of the treatment is to reduce the limitations caused by the condition to allow you to carry on working and take control over the rest of your life.

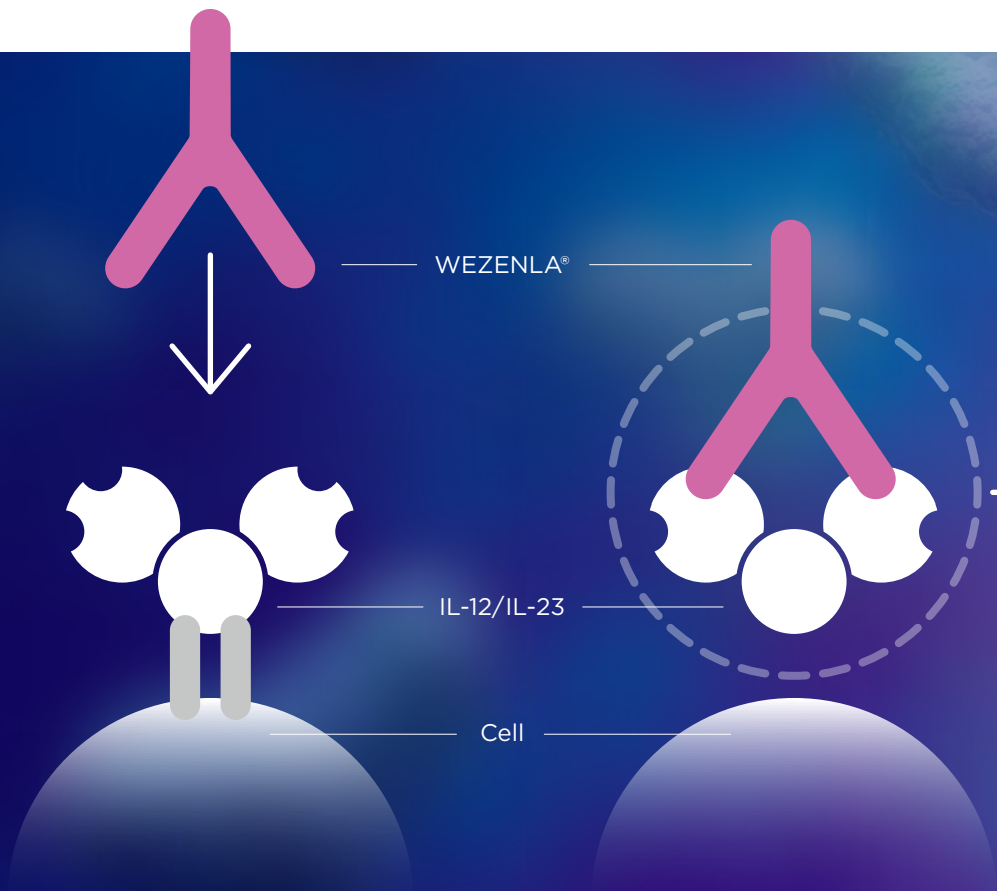
Biopharmaceutical therapy using living cells



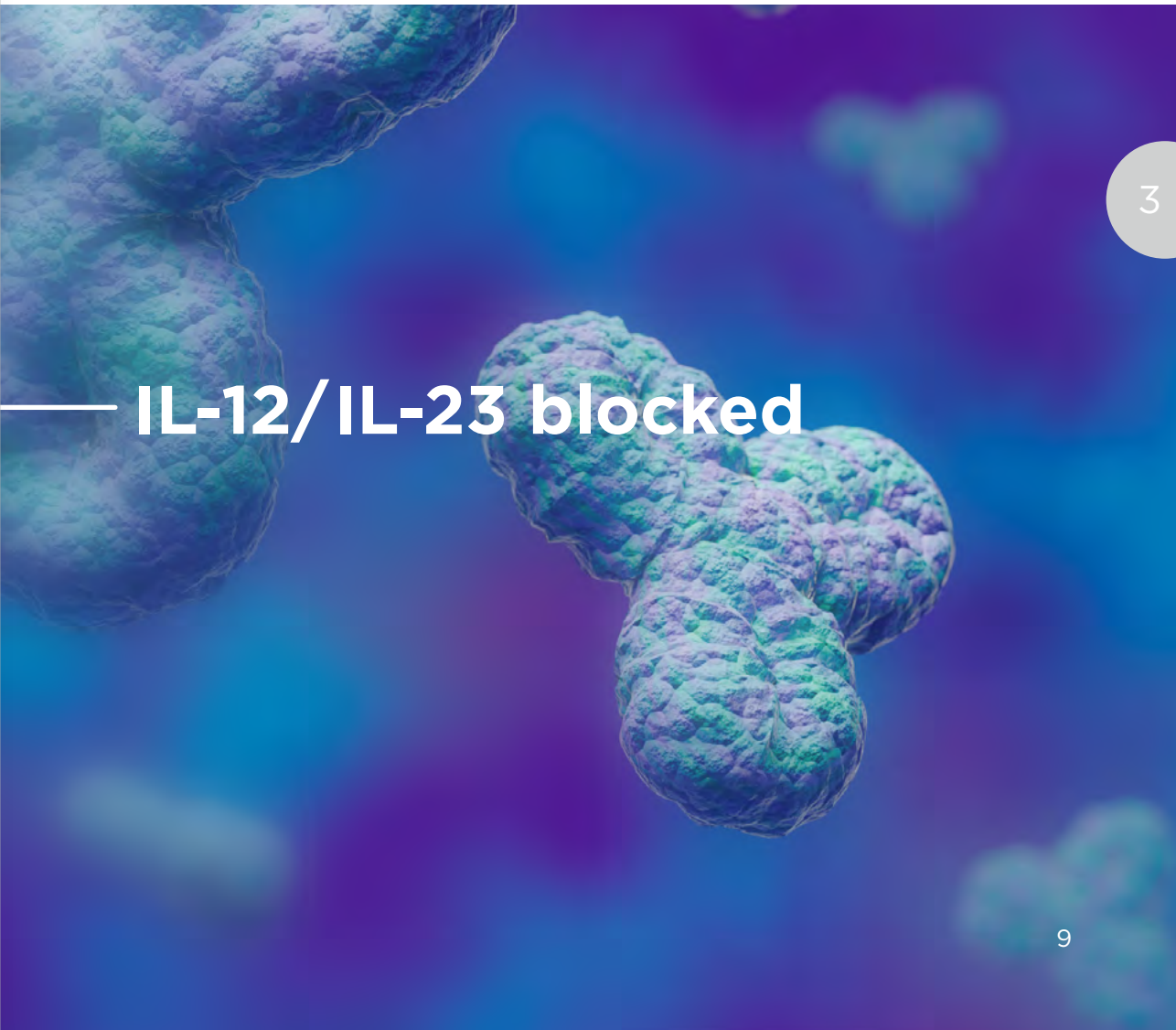
Ustekinumab is a biologic. This means the active substance is produced from living organisms that have been modified using the latest production techniques. These techniques are used to produce molecules that are similar to those in our body, precisely targeting human metabolic processes.

3 Where in the body does WEZENLA® work?

In inflammatory disorders, the body's normal immune response is compromised. This means, for example, that the body produces too much of two specific proteins: Interleukin-12 (IL-12) and interleukin-23 (IL-23). This overproduction can lead to your immune system attacking parts of your body, which causes inflammation.⁴



The active substance, ustekinumab, binds to excess IL-12 and IL-23 and blocks it.



IL-12/IL-23 blocked

4 How is WEZENLA® administered?

WEZENLA® is administered by subcutaneous injection or intravenous infusion, depending on your condition. Ask your doctor how you will receive WEZENLA® initially.^{1,7}

Plaque psoriasis and psoriatic arthritis

If you suffer from plaque psoriasis or psoriatic arthritis you will receive WEZENLA® in 2 injections 4 weeks apart, followed by injections every 12 weeks. You will also be monitored to see how you respond to the active substance, ustekinumab.

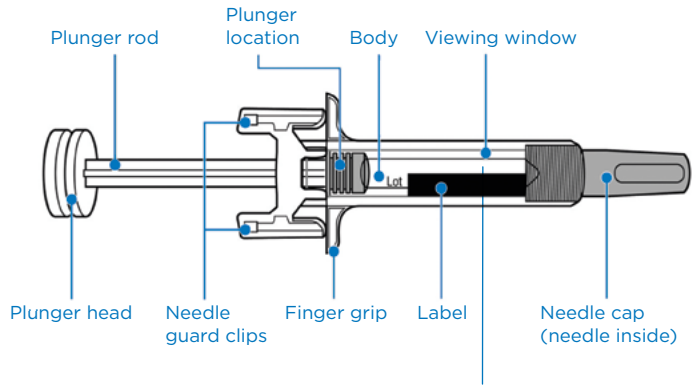
Crohn's disease

If you suffer from Crohn's disease your treatment starts with a one-off infusion via the vein in your arm. This will be administered by a health-care professional at a medical practice or hospital clinic and takes around one hour to complete. After the initial infusion, you will receive your next dose as an injection under the skin 8 weeks later, and then every 12 weeks thereafter.

Home administration possible

If you are happy to do so you can inject WEZENLA® subcutaneously yourself following a brief training session at your medical practice. Subcutaneous means “under the skin”.

Take control whenever you want



Inspection window

The liquid should be clear
and colourless or light yellow.

Storage and expiry date¹

The medication must be stored
in a refrigerator (2–8°C), in its original
box. It is not allowed to freeze.

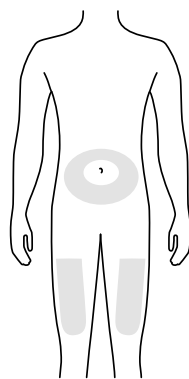
Do not put the syringe back into
the refrigerator once it has reached
room temperature.



If necessary, the
medicinal product can
also be stored at room
temperature (up to 30°C),
protected from light
and used within
30 days.

How is WEZENLA® administered?

You can inject WEZENLA® anywhere on the front of your thighs and belly (except 5 cm around your belly button). Avoid areas with scars, stretch marks or where skin is tender, bruised, red, or hard. If possible, do not use areas of skin that show sign of psoriasis.

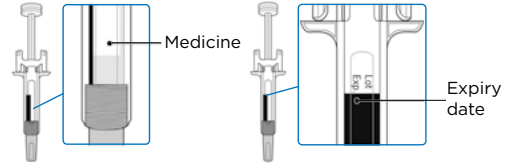


Step 1: Prepare

Remove the prefilled syringe from the refrigerator approximately half an hour before injecting. Have an alcohol wipe and a cotton ball or dressing gauze ready as well as a plaster.

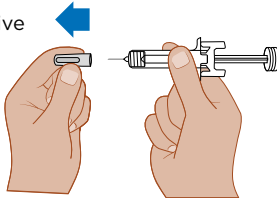
Step 2: Visual check

The prefilled syringe should only be used if the liquid is clear to opalescent, colourless to light yellow. Check the expiry date. Disinfect the chosen injection site with the alcohol wipe.



Stage 3: Remove protective needle cap

Ease the protective needle cap off gently in a straight line.



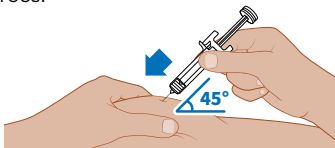
Step 4: Prepare the surface of the skin

Pinch the skin with your thumb and forefinger to make a flap about 5 cm wide.



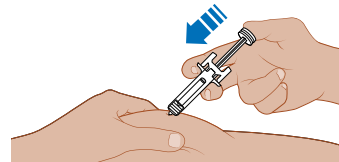
Step 5: Insert prefilled syringe

Keep your skin pinched whilst injecting. Hold the prefilled syringe by the syringe body and insert the needle into the pinched skin at an angle of 45 degrees.



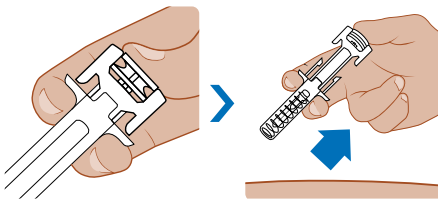
Step 6: Inject prefilled syringe

Push the plunger head slowly and evenly down to the bottom until it stops moving and the plunger clicks into place.



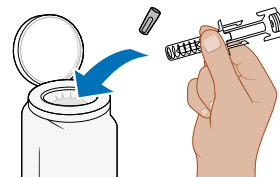
Step 7: Remove prefilled syringe

With your thumb on the plunger head, carefully ease the syringe out of your skin in a straight line.



Step 8: Disposal and aftercare

Dispose of the used prefilled syringe in the sharps disposal container*. Use a plaster to stop any bleeding at the injection site.



Detailed information can be found in the package insert.

* Patients can obtain a sharps disposal container on request as part of the treatment care programme.

5 Where to get further advice

Support for your treatment from the start



Chronic inflammatory conditions 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. AmgenCare by Amgen offers a comprehensive and free-of-charge patient support programme that covers the following areas, among others:

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

These materials and more are available at:
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're very 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 see 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.

Important addresses

Deutsche Morbus Crohn und Colitis ulcerosa Vereinigung (German Crohn's & Colitis Foundation)
www.dccv.de

Deutsche Rheuma-Liga (German League Against Rheumatism)
www.rheuma-liga.de

Deutscher Psoriasis Bund e.V.
www.psoriasis-bund.de

References

1. Summary of Product Characteristics for WEZENLA®.
2. www.rheuma-liga.de/rheuma/krankheitsbilder/psoriasis-arthritis. Last accessed: June 2024.
3. Approved by the European Medicines Agency (EMA) on 20.06.2024
4. Sun L et al. Interleukin 12 (IL-12) family cytokines: role in immune pathogenesis and treatment of CNS autoimmune disease. *Cytokine*. 2015;75(2):249–255.
5. Crohn's and Colitis Foundation. Fact Sheet: Biologics. <https://www.crohnscolitisfoundation.org/sites/default/files/2023-11/Biologics%2011.2023.pdf>. Last accessed: June 2024.
6. Lee KM et al. The role of interleukin (IL)-23 in regulating pain in arthritis. *Arthritis Res Ther*. 2022;24(1):89.
7. Instructions for Use for WEZENLA®.



Glossary

Autoimmune disorder

An autoimmune disorder occurs when an individual's immune system malfunctions and the body attacks its own tissue.

Biologic

The term "biologic" comes from "biological" and means the same as "biopharmaceutical".

Biopharmaceutical

These are drugs produced using biotechnology. Biotechnology uses whole organisms or parts of organisms to produce materials. The organisms will often be microorganisms such as bacteria or yeasts, but mammal cell cultures or even plants are sometimes used as well. The kind of organism used depends on the product that is to be manufactured.

Chronic inflammatory disease

Many chronic inflammatory diseases are referred to as autoimmune disorders - where the body's own immune system responds in the wrong way. White blood

cells identify healthy tissue as a hazard, not just foreign bodies, and attack it.

Infusion

An infusion involves continuous, mostly intravenous administration of liquid medication.

Injection

An injection involves injecting a sterile liquid substance into the body through a syringe fitted with a cannula.

Interleukins

Interleukins are a group of cellular messenger substances in the body's immune system.

Intravenous (IV)

Intravenous administration refers to the injection of medication or a fluid directly into the vein.

Subcutaneous (SC)

A subcutaneous injection involves injecting the medication or a fluid under the skin.

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