



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/398237/2025
EMA/H/C/006621

Gotenfia (*golimumab*)

An overview of Gotenfia and why it is authorised in the EU

What is Gotenfia and what is it used for?

Gotenfia is an anti-inflammatory medicine. It is used to treat the following diseases:

- active rheumatoid arthritis (a disease causing inflammation of the joints). Gotenfia is used in combination with methotrexate (a medicine that acts on the immune system). It can be used in adults who have not responded adequately to other treatments, including methotrexate, whose disease is moderate to severe, and in adults who have not been previously treated with methotrexate whose disease is severe and progressive (gets worse over time);
- active and progressive psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints). Gotenfia is used in adults who have not responded adequately to other treatments. It can be used alone or in combination with methotrexate;
- axial spondyloarthritis (a disease causing inflammation and pain in the joints of the spine). Gotenfia is used in:
 - adults with severe active ankylosing spondylitis who have not responded adequately to other treatments;
 - adults with severe non-radiographic axial spondyloarthritis (when there are objective signs of inflammation, but no abnormalities seen on x-ray) who have not responded adequately or are intolerant to anti-inflammatory medicines called non-steroidal anti-inflammatory drugs (NSAIDs);
- moderately to severely active ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut). Gotenfia is used in adults who have not responded adequately to, or cannot use, conventional treatment;
- polyarticular juvenile idiopathic arthritis (a rare childhood disease causing inflammation of many joints). Gotenfia is used in combination with methotrexate. It is used in children from 2 years of age who have not responded adequately to treatment with methotrexate.

Gotenfia contains the active substance golimumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Gotenfia is highly similar to another biological medicine (the 'reference

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medicine') that is already authorised in the EU. The reference medicine for Gotenfia is Simponi. For more information on biosimilar medicines, see [here](#).

How is Gotenfia used?

Gotenfia can only be obtained with a prescription, and treatment must be started and supervised by a doctor who has experience in the diagnosis and treatment of the diseases that Gotenfia is used to treat.

The medicine is available as pre-filled syringes containing a solution for injection under the skin. The recommended dose depends on the disease Gotenfia is used to treat and the patient's response. Children under 40 kg with polyarticular juvenile idiopathic arthritis who need lower doses should use another medicine containing the same active substance, golimumab, to allow the dose to be adjusted as needed.

After training, patients may inject themselves with Gotenfia if their doctor agrees.

For more information about using Gotenfia, see the package leaflet or contact your doctor or pharmacist.

How does Gotenfia work?

The active substance in Gotenfia, golimumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) that is found in the body. Golimumab has been designed to attach to and block a substance in the body called tumour necrosis factor alpha. This substance is involved in causing inflammation and is found at high levels in patients with the diseases that Gotenfia is used to treat. By blocking tumour necrosis factor alpha, golimumab reduces the inflammation and other symptoms of these diseases.

What benefits of Gotenfia have been shown in studies?

Laboratory studies comparing Gotenfia with Simponi have shown that the active substance in Gotenfia is highly similar to that in Simponi in terms of structure, purity and biological activity. Studies have also shown that giving Gotenfia produces similar levels of the active substance in the body to those seen with Simponi.

In addition, a study involving 704 adults with active psoriatic arthritis showed that Gotenfia was as effective as Simponi at reducing the severity of the disease. The main measure of effectiveness was the number of people who had at least a 20% improvement in signs and symptoms of the disease (ACR20) after 8 weeks of treatment. Although after 8 weeks of treatment the ACR20 response rate was higher in people given Gotenfia (around 75%) than in those given Simponi (around 63%), the ACR20 response rates were comparable after 14 weeks (around 79% for Gotenfia and around 77% for Simponi) and 52 weeks of treatment (around 90% for Gotenfia and around 88% for Simponi). The comparable effectiveness of Gotenfia and Simponi was also supported by similar improvements in symptoms and disease activity measured with another scale called the DAS28-CRP score from week 14 to week 52 of treatment.

Because Gotenfia is a biosimilar medicine, the studies on the effectiveness of golimumab carried out with Simponi do not all need to be repeated for Gotenfia.

What are the risks associated with Gotenfia?

The safety of Gotenfia has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Simponi.

For the complete list of side effects and restrictions with Gotenfia, see the package leaflet.

The most common side effects with golimumab (which may affect more than 1 in 10 people) include upper respiratory tract infections such as infections of the nose, throat or voice box.

Some side effects can be serious. The most serious side effects with golimumab include serious infections, such as sepsis (blood infection), pneumonia (lung infection), tuberculosis and infections due to fungi or yeasts, demyelinating disorders (disorders suggesting damage to the protective sheath around nerves, such as changes to vision and weak arms or legs), re-activation of hepatitis B (a disease of the liver due to infection with the hepatitis B virus), congestive heart failure (a heart disease), lupus-like syndrome (an autoimmune disease), blood reactions, severe allergic reactions, vasculitis (inflammation of the blood vessels), lymphoma and leukaemia (types of cancer of the white blood cells).

Gotenfia must not be used in patients with tuberculosis, other severe infections, or moderate to severe heart failure (an inability of the heart to pump enough blood around the body). Due to an increased risk of infection, patients taking Gotenfia must be monitored closely for infections, including tuberculosis, during and for up to 5 months after treatment.

Why is Gotenfia authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Gotenfia has a highly similar structure, purity and biological activity to Simponi and is distributed in the body in the same way. In addition, studies in active psoriatic arthritis have shown that Gotenfia and Simponi are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Gotenfia will have the same effects as Simponi in its authorised uses. Therefore, the Agency's view was that, as for Simponi, the benefits of Gotenfia outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Gotenfia?

Patients treated with Gotenfia must be given a patient card that summarises the safety information about the medicine and when to seek medical advice. Patients should show this card when seeing a healthcare professional, so that they are aware that the patient is using Gotenfia.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Gotenfia have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Gotenfia are continuously monitored. Suspected side effects reported with Gotenfia are carefully evaluated and any necessary action taken to protect patients.

Other information about Gotenfia

Gotenfia received a marketing authorisation valid throughout the EU on 10 February 2026.

Further information on Gotenfia can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/gotenfia.

This overview was last updated in 01-2026.