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Gobivaz (*golimumab*)

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

What is Gobivaz and what is it used for?

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

- active rheumatoid arthritis (a disease causing inflammation of the joints). Gobivaz 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 previously been treated with methotrexate whose disease is severe and progressive;
- active and progressive psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints). Gobivaz 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), including:
  - 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). Gobivaz 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). Gobivaz 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.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

How is Gobivaz used?

Gobivaz 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 Gobivaz is used to treat.

The medicine is available as pre-filled pens and syringes containing a solution for injection under the skin. The recommended dose depends on the disease Gobivaz is used to treat and the response of the patient. 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 Gobivaz if their doctor agrees.

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

How does Gobivaz work?

The active substance in Gobivaz, 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 Gobivaz is used to treat. By blocking tumour necrosis factor alpha, golimumab reduces the inflammation and other symptoms of these diseases.

What benefits of Gobivaz have been shown in studies?

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

In addition, a study involving 502 adults with moderate to severely active rheumatoid arthritis showed that Gobivaz was as effective as Simponi at reducing the severity of the disease, when both were taken with methotrexate. The main measure of effectiveness was the DAS28-CRP score. Scores range from 0 to 9.4; a decrease in the score means an improvement in symptoms and better disease control. After 16 weeks of treatment, those given Gobivaz had on average a reduction of around 2.9 in the DAS28-CRP score compared with a reduction of around 3 for those given Simponi.

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

What are the risks associated with Gobivaz?

The safety of Gobivaz 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 full list of side effects and restrictions with Gobivaz, see the package leaflet.

The most common side effects with Gobivaz (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 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), and lymphoma and leukaemia (types of cancer of the white blood cells).

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

Why is Gobivaz authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Gobivaz 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 rheumatoid arthritis have shown that Gobivaz and Simponi are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Gobivaz will have the same effects as Simponi in its authorised uses. Therefore, the Agency's view was that, as for Simponi, the benefits of Gobivaz 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 Gobivaz?

Patients treated with Gobivaz must be given a reminder 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 Gobivaz.

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

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

Other information about Gobivaz

Gobivaz received a marketing authorisation valid throughout the EU on 17 November 2025.

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

This overview was last updated in 10-2025.