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**EPAR summary for the public**

# Simponi

golimumab

This is a summary of the European public assessment report (EPAR) for Simponi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Simponi.

For practical information about using Simponi, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Simponi and what is it used for?

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

- active rheumatoid arthritis (a disease causing inflammation of the joints). Simponi 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 patients 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). Simponi 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);

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- moderately to severely active ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut). Simponi 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). Simponi is used in combination with methotrexate. It is used in children with a body weight of at least 40 kg who have not responded adequately to treatment with methotrexate.

Simponi contains the active substance golimumab.

## How is Simponi used?

Treatment with Simponi must be initiated and supervised by a qualified doctor who has experience in the diagnosis and treatment of the diseases that Simponi is used to treat.

Simponi is available as pre-filled pens and syringes (50 and 100 mg) containing a solution for injection under the skin. The recommended dose depends on the disease Simponi is used to treat and the response of the patient.

After training, patients may inject themselves with Simponi if their doctor agrees. For more information, see the package leaflet.

The medicine can only be obtained with a prescription.

## How does Simponi work?

The active substance in Simponi, golimumab, is a monoclonal antibody. A monoclonal antibody is an 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 chemical messenger in the body called tumour necrosis factor alpha (TNF-α). This messenger is involved in causing inflammation and is found at high levels in patients with the diseases that Simponi is used to treat. By blocking TNF-α, golimumab reduces the inflammation and other symptoms of these diseases.

## What benefits of Simponi have been shown in studies?

For rheumatoid arthritis, Simponi was compared with placebo (a dummy treatment) in three studies involving 1,542 patients with moderate to severe rheumatoid arthritis, including patients who had not received or responded adequately to other treatments. The main measures of effectiveness were based on the number of patients who had 20 or 50% reductions in the number and severity of symptoms after 14 or 24 weeks. The other main measure of effectiveness, used in one study, was the improvement in the patient's ability to carry out everyday tasks (such as dressing, eating, and walking) after 24 weeks.

In the first study, in which patients were also given methotrexate, after 14 weeks, 55% patients who received Simponi (49 out of 89) achieved 20% reductions compared with 33% (44 out of 133) of patients who received placebo. This study also showed that patients who received Simponi had greater improvements in carrying out everyday tasks. In the second study, after 14 weeks, 35% of patients who received Simponi alone (54 out of 153) achieved 20% reductions compared with 18% of patients who received placebo (28 out of 155). In the third study, in patients who had not been previously treated with either methotrexate or another anti-TNF-α, after 24 weeks, 40% of patients (64 out of 159) who received Simponi with methotrexate achieved 50% reductions compared with 29% of

patients (47 out of 160) who received placebo and methotrexate. Data from X-rays taken before and after two years of treatment showed less joint damage in patients receiving Simponi than in those receiving placebo.

For psoriatic arthritis, Simponi was compared with placebo over 24 weeks in one main study involving 405 patients who had not responded adequately to other treatments. The main measure of effectiveness was based on the number of patients who had 20% reductions in the number and severity of symptoms after 14 weeks. Of the patients who received Simponi, 51% (74 out of 146) had 20% reductions after 14 weeks, compared with 9% of patients who were given placebo (10 out of 113).

For ankylosing spondylitis, Simponi was compared with placebo over 24 weeks in one main study involving 356 patients who had not responded adequately to other treatments. The main measure of effectiveness was based on the number of patients who had 20% reductions in the number and severity of symptoms after 14 weeks. Of the patients who received Simponi, 59% (82 out of 138) had 20% reductions after 14 weeks, compared with 22% of patients who were given placebo (17 out of 78).

For non-radiographic axial spondyloarthritis, Simponi was compared with placebo over 16 weeks in one main study involving 198 patients who had the disease without evidence of ankylosing spondylitis but with signs of inflammation and who had not responded adequately to treatment with NSAIDs. The main measure of effectiveness was based on the number of patients who had 20% reductions in the number and severity of symptoms after 16 weeks. Of the patients who received Simponi, 71% (69 out of 97) had 20% reductions after 16 weeks, compared with 40% of patients who were given placebo (40 out of 100).

For ulcerative colitis, Simponi was compared with placebo in two main studies in patients who had not responded to or could not use other treatments. The first study, involving 1,065 patients, compared different doses of Simponi with placebo as induction treatment. The second study, involving 1,228 patients, compared Simponi 50 or 100 mg with placebo as maintenance treatment. The main measure of effectiveness was the number of patients who responded to treatment, based on the number and severity of symptoms. This was assessed after 6 weeks in the first study and after 54 weeks in the second study. In the first study, around 51% of patients receiving induction treatment with Simponi (starting at 200 mg) responded to treatment after 6 weeks, compared with around 30% of patients given placebo. In the second study, around 50% of patients receiving maintenance treatment with Simponi 100 mg and around 47% of those given Simponi 50 mg responded to treatment after 54 weeks, compared with around 31% of patients given placebo.

For polyarticular juvenile idiopathic arthritis, 173 patients between 2 and 18 years old who had not responded adequately to treatment with methotrexate were treated for 12 weeks with Simponi and methotrexate. Of these patients, 87% of (151 out of 173) had 30% reduction in the number and severity of symptoms after 16 weeks. Treatment with Simponi and methotrexate was not compared with placebo or any other treatment.

## What are the risks associated with Simponi?

The most common side effects with Simponi are upper respiratory tract infections such as infections of the nose, throat or voice box. 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 liver disease), congestive

heart failure (a heart disease), lupus-like syndrome, blood reactions, severe allergic reactions, vasculitis (inflammation of the blood vessels), and lymphoma and leukaemia (types of cancer of the white blood cells). For the full list of all side effects reported with Simponi, see the package leaflet.

Simponi 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 Simponi must be monitored closely for infections, including tuberculosis, during and for up to five months after treatment. For the full list of restrictions with Simponi, see the package leaflet.

## Why is Simponi approved?

The CHMP decided that Simponi's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that markets Simponi must provide educational packs for doctors who prescribe Simponi with information on the safety of the medicine. Patients treated with Simponi must also be given a special alert card that summarises the safety information about the medicine.

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

## Other information about Simponi

The European Commission granted a marketing authorisation valid throughout the European Union for Simponi on 1 October 2009.

The full EPAR for Simponi can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Simponi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.