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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Simponi

golimumab

Table of contents

AUTHORISED
This medicine is authorised for use in the European Union.

Overview

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);

- 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 from 2 years of age who have not responded adequately to treatment with methotrexate.

Simponi contains the active substance golimumab.

How is Simponi used?

Simponi is available as pre-filled pens and syringes 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.

Simponi can only be obtained with a prescription and treatment 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. After training, patients may inject themselves with Simponi if their doctor agrees.

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

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 substance in the body called tumour necrosis factor alpha (TNF-a). This substance 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-a, golimumab reduces the inflammation and other symptoms of these diseases.

What benefits of Simponi have been shown in studies?

Simponi has been shown to be effective at reducing the number and severity of symptoms in patients with the conditions for which it is authorised.

Rheumatoid arthritis

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.

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 (such as dressing, eating and walking) after 24 weeks. In the second study, after 14 weeks, 35% of patients who received Simponi alone (54 out of 153) achieved 20% reductions in the number and severity of symptoms 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-a, 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.

Psoriatic arthritis

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. Of the patients who received Simponi, 51% (74 out of 146) had 20% reductions in the number and severity of symptoms after 14 weeks, compared with 9% of patients who were given placebo (10 out of 113).

Ankylosing spondylitis

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. Of the patients who received Simponi, 59% (82 out of 138) had 20% reductions in the number and severity of symptoms after 14 weeks, compared with 22% of patients who were given placebo (17 out of 78).

Axial spondyloarthritis

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. Of the patients who received Simponi, 71% (69 out of 97) had 20% reductions in the number and severity of symptoms after 16 weeks, compared with 40% of patients who were given placebo (40 out of 100).

Ulcerative colitis

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.

Polyarticular juvenile idiopathic arthritis

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 disease of the liver due to infection with the hepatitis B virus), 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 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 5 months after treatment. For the full list of restrictions with Simponi, see the package leaflet.

Why is Simponi authorised in the EU?

The European Medicines Agency decided that Simponi's benefits are greater than its risks and that it can be authorised for use in the EU.

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

Patients treated with Simponi 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 Simponi.

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.

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

Other information about Simponi

Simponi received a marketing authorisation valid throughout the EU on 1 October 2009.

Simponi : EPAR - Summary for the public (PDF/91.92 KB)

First published: 20/10/2009
Last updated: 13/03/2019
EMA/552/2019

Available languages (22)

Simponi : EPAR - Risk-management-plan summary (PDF/161.7 KB)

First published: 23/10/2018
Last updated: 17/10/2019

More detail is available in the summary of product characteristics

This EPAR was last updated on 16/11/2021

Authorisation details

Name
Simponi
Agency product number
EMEA/H/C/000992
Active substance
Golimumab
International non-proprietary name (INN) or common name
golimumab

Therapeutic area (MeSH)

- Arthritis, Psoriatic
- Spondylitis, Ankylosing
- Colitis, Ulcerative
- Arthritis, Rheumatoid

Anatomical therapeutic chemical (ATC) code

L04AB06

Marketing-authorisation holder

Janssen Biologics B.V.

Revision

42

Date of issue of marketing authorisation valid throughout the European Union

01/10/2009

Contact address

Einsteinweg 101
NL-2333 CB Leiden
The Netherlands

Product information

16/09/2021 Simponi - EMEA/H/C/000992 - P46/037

Simponi : EPAR - Product information (PDF/5.58 MB)

First published: 20/10/2009
Last updated: 09/11/2021

Available languages (24)

Contents

- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Simponi : EPAR - All Authorised presentations (PDF/35.59 KB)

First published: 20/10/2009
Last updated: 13/03/2019

Available languages (24)

Simponi : EPAR - Conditions imposed on member states for safe and effective use - Annex IV (PDF/24.75 KB)

First published: 20/10/2009
Last updated: 20/10/2009

Available languages (21)

Pharmacotherapeutic group

Immunosuppressants

Therapeutic indication

Rheumatoid arthritis (RA)

Simponi, in combination with methotrexate (MTX), is indicated for:

- the treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate.
- the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with MTX.

Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X ray and to improve physical function.

For information regarding the polyarticular juvenile idiopathic arthritis indication, please see the

Simponi 50 mg SmPC.

Psoriatic arthritis (PsA)

Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous DMARD therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X ray in patients with polyarticular symmetrical subtypes of the disease (see section 5.1) and to improve physical function.

Axial spondyloarthritis

Ankylosing spondylitis (AS)

Simponi is indicated for the treatment of severe, active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Non radiographic axial spondyloarthritis (nr Axial SpA)

Simponi is indicated for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

Ulcerative colitis (UC)

Simponi is indicated for treatment of moderately to severely active ulcerative colitis in adult patients who have had an inadequate response to conventional therapy including corticosteroids and 6 mercaptopurine (6 MP) or azathioprine (AZA), or who are intolerant to or have medical contraindications for such therapies.

Juvenile idiopathic arthritis

Polyarticular juvenile idiopathic arthritis (pJIA)

Simponi in combination with methotrexate (MTX) is indicated for the treatment of polyarticular juvenile idiopathic arthritis in children 2 years of age and older, who have responded inadequately to previous therapy with MTX.

Rheumatoid arthritis (RA)

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Assessment history

Changes since initial authorisation of medicine

Simponi : EPAR - Procedural steps taken and scientific information after authorisation (PDF/265.78 KB)

First published: 19/04/2010
Last updated: 09/11/2021

Simponi-H-C-992-P46-037 : EPAR - Assessment Report - Variation (PDF/561.98 KB)

Adopted

First published: 16/11/2021
EMA/527502/2021

Simponi-H-C-992-X-0083-G: EPAR - Assessment Report - Extension (PDF/1.34 MB)

Adopted

First published: 13/03/2019
EMA/898638/2018

CHMP post-authorisation summary of positive opinion for Simponi (X-83-G) (PDF/68.48 KB)

Adopted

First published: 14/12/2018
EMA/CHMP/833171/2018

Simponi-H-C-992-II-0063 : EPAR - Assessment Report - Variation (PDF/6.32 MB)

Adopted

First published: 11/08/2016
Last updated: 11/08/2016
EMA/CHMP/404217/2016

CHMP post-authorisation summary of positive opinion for Simponi (PDF/77.88 KB)

Adopted

First published: 27/05/2016
Last updated: 27/05/2016
EMA/CHMP/339032/2016

Simponi-H-C-992-II-0061 : EPAR - Assessment Report - Variation (PDF/2.19 MB)

Adopted

First published: 12/08/2015
Last updated: 12/08/2015
EMA/CHMP/422136/2015

CHMP post-authorisation summary of positive opinion for Simponi (PDF/72.94 KB)

Adopted

First published: 22/05/2015
Last updated: 22/05/2015
EMA/CHMP/308417/2015

Simponi-H-C-992-PSUV-0058: EPAR - Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation (PDF/70.19 KB)

First published: 05/02/2015
Last updated: 05/02/2015
EMA/CHMP/81751/2015

Simponi-H-C-992-II-0039 : EPAR - Assessment Report - Variation (PDF/1.43 MB)

Adopted

First published: 23/10/2013
Last updated: 23/10/2013
EMA/640422/2013

CHMP post-authorisation summary of positive opinion for Simponi (PDF/75.63 KB)

Adopted

First published: 26/07/2013
Last updated: 26/07/2013
EMA/CHMP/365481/2013

Simponi-H-C-992-II-0025: EPAR - Assessment Report - Variation (PDF/672.46 KB)

Adopted

First published: 20/07/2011
Last updated: 20/07/2011

CHMP post-authorisation summary of positive opinion for Simponi (PDF/53.15 KB)

Adopted

First published: 15/04/2011
Last updated: 15/04/2011
EMA/CHMP/295989/2011

Simponi-H-C-992-II-0008: EPAR - Assessment Report- Variation (PDF/1.87 MB)

Adopted

First published: 18/02/2011
Last updated: 18/02/2011
EMA/CHMP/58067/2011

CHMP post-authorisation summary of positive opinion for Simponi (PDF/56.84 KB)

Adopted

First published: 17/12/2010
Last updated: 17/12/2010
EMA/CHMP/793256/2010

Initial marketing-authorisation documents

Simponi : EPAR - Public assessment report (PDF/703.06 KB)

First published: 20/10/2009
Last updated: 20/10/2009

Committee for medicinal products for human use, summary of positive opinion for Simponi (PDF/80.36 KB)

First published: 25/06/2009
Last updated: 25/06/2009
EMEA/CHMP/362870/2009

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 10-13 December 2018

  14/12/2018
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23-26 May 2016

  27/05/2016

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 18-21 May 2015
  22/05/2015
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2013
  26/07/2013
- European Medicines Agency increases transparency of ongoing applications for human medicines
  07/11/2012

Related content

- Simponi: Withdrawn application
- Simponi: Paediatric investigation plan
- Simponi: Paediatric investigation plan

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How to find us

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