EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Stelara

*ustekinumab*

Table of contents





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

## Overview

Stelara is a medicine used to treat:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in adults and children above the age of 6 years whose condition has not improved with, or who cannot use, other systemic (whole-body) psoriasis treatments, such as ciclosporin, methotrexate or PUVA (psoralen ultraviolet A). PUVA is a type of treatment where the patient receives a medicine called psoralen, before being exposed to ultraviolet light;
- active psoriatic arthritis (inflammation of the joints associated with psoriasis) in adults, when the condition has not improved enough with other treatments called disease-modifying anti-rheumatic drugs (DMARDs). Stelara may be used alone or combined with methotrexate (a DMARD);
- moderately to severely active Crohn's disease (a disease-causing inflammation of the gut) in adults whose condition has not improved enough with other treatments for Crohn's disease or who cannot receive such treatments;
- moderately to severely active ulcerative colitis (inflammation of the large intestine causing ulceration and bleeding) in adults whose condition has not improved enough with other treatments for ulcerative colitis or who cannot receive such treatments.

Stelara contains the active substance ustekinumab.

**How is Stelara used?**

Stelara can only be obtained with a prescription and should be given under the supervision of a doctor who has experience in diagnosing and treating the diseases that Stelara is used for.

In plaque psoriasis and psoriatic arthritis, Stelara is injected under the skin. For adults the usual dose is 45 mg, whereas in children with plaque psoriasis the dose depends on their bodyweight. The dose in patients weighing over 100 kg is 90 mg for psoriasis, and this dose may also be considered for psoriatic arthritis. The first injection is followed by a further injection 4 weeks later, and then an injection every 12 weeks.

In Crohn's disease and ulcerative colitis, treatment is started with Stelara infusion (drip) into a vein over at least 1 hour. The dose depends on the patient's bodyweight. Eight weeks after the first infusion, a dose of 90 mg is injected under the skin. Patients then continue with Stelara injected under the skin every 8 or 12 weeks depending on how well the treatment is working.

Patients or their caregivers may inject Stelara under the skin once they have been trained, if their doctor thinks that this is appropriate. For more information about using Stelara, see the package leaflet or contact your doctor or pharmacist.

**How does Stelara work?**

The active substance in Stelara, ustekinumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific target in the body. Ustekinumab attaches to 2 messenger molecules in the immune system called interleukin 12 and interleukin 23. Both are involved in inflammation and other processes that are important in psoriasis, psoriatic arthritis, Crohn's disease and ulcerative colitis. By blocking their activity, ustekinumab reduces the activity of the immune system and the symptoms of the disease.

**What benefits of Stelara have been shown in studies?**

**Plaque psoriasis**

In the treatment of moderate to severe plaque psoriasis, Stelara was more effective than placebo (a dummy treatment) in 2 main studies involving a total of 1,996 adult patients. In over half of these patients, other treatments for psoriasis had not worked, were not tolerated or could not be taken by the patients. The main measure of effectiveness was the number of patients whose symptom score improved by 75% or more after 12 weeks. Taking the results of the 2 main studies in adults together, symptoms improved in around 69% of the patients receiving Stelara after 12 weeks, compared with around 3% of the patients receiving placebo.

Longer-term results from these studies showed that with continuous treatment for 5 years, improvement of symptoms with Stelara is maintained. A study comparing Stelara with etanercept (another medicine used for psoriasis) found that Stelara is more effective than etanercept after 12 weeks of treatment.

Two studies were carried out in children with moderate to severe plaque psoriasis. The main measure of effectiveness for both studies was the number of patients whose symptom score improved after treatment for 12 weeks. The first study involved 110 children aged between 12 and 18 years. The children received placebo or Stelara. Around 69% of children who received Stelara achieved a score of cleared or minimal, compared with 5% of patients receiving placebo. The second study involved 44 children aged between 6 and 11 years. All children received Stelara and this was not compared to any other treatment. Around 77% of children achieved a score of cleared or minimal.

**Psoriatic arthritis**

In the treatment of active psoriatic arthritis, Stelara was compared with placebo in 2 main studies involving a total of 927 adult patients whose condition was not controlled well enough with previous treatments. In both studies, the main measure of effectiveness was the number of patients whose symptom score improved after 24 weeks. In the first study, symptom score improved in around 42% of those given Stelara 45 mg and 50% of those given 90 mg, compared with around 23% of those given placebo. In the second study, symptom score improved in around 44% of those given either dose of Stelara, compared with around 20% of those given placebo.

**Crohn's disease**

In the treatment of Crohn's disease, Stelara (given by infusion) was compared with placebo in 2 main studies involving 1,369 patients with moderately to severely active disease. The main measure of effectiveness was the number of patients whose symptom score improved 6 weeks after the infusion. In the first study, symptom score improved in around 34% patients who received Stelara compared with 21% of patients receiving placebo. In the second study the figures were 56% for Stelara and 29% for placebo.

Some patients from the 2 main studies went on to receive Stelara (injected under the skin) every 8 or 12 weeks, or placebo. After 44 weeks of starting treatment by injection under the skin, 53% of patients on Stelara every 8 weeks and 49% of patients on Stelara every 12 weeks had a significant reduction in symptoms of Crohn's disease, compared with 36% of patients on placebo.

**Ulcerative colitis**

In the treatment of ulcerative colitis, Stelara (given by infusion) was compared with placebo in 2 main studies. The first study involved 961 patients with moderately to severely active disease. The main measure of effectiveness was the number of patients whose symptoms were gone or almost gone 8 weeks after the infusion. Symptoms were gone or almost gone in 16% of patients who received Stelara compared with 5% of patients receiving placebo.

In the second study, a total of 523 patients from the first study whose symptoms had improved with Stelara went on to receive the medicine (injected under the skin) every 8 or 12 weeks, or placebo. After 44 weeks of starting treatment by injection under the skin, symptoms of ulcerative colitis were gone or almost gone in 44% of patients on Stelara every 8 weeks and 38% of patients on Stelara every 12 weeks, compared with 24% of patients on placebo.

**What are the risks associated with Stelara?**

The most common side effects with Stelara (seen in more than 1 in 20 during clinical trials) are headache and nasopharyngitis (inflammation of the nose and throat). The most serious side effect reported with Stelara is serious hypersensitivity (allergic reaction). For the full list of side effects of Stelara, see the package leaflet.

Stelara must not be used in patients who have an active infection that the doctor considers important. For the full list of restrictions, see the package leaflet.

**Why is Stelara approved?**

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

The Agency considered that studies had shown that Stelara was effective in the treatment of adults and children over 6 years of age with moderate to severe plaque psoriasis in whom other treatments had not worked or could not be used.

For adults with psoriatic arthritis whose condition had not improved enough with DMARDs, the Agency noted that limited treatments were available and considered that Stelara would be of benefit in these patients.

In Crohn's disease, the effects of Stelara in reducing symptoms in patients in whom other treatments had not worked or could not be used were considered important, also given the unmet medical need of these patients. The side effects of the medicine were considered manageable.

In ulcerative colitis, studies showed that Stelara was effective in treatment of patients in whom other treatments had not worked or could not be used. The side effects were as expected for this medicine.

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

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

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

**Other information about Stelara**

Stelara received a marketing authorisation valid throughout the EU on 16 January 2009.

Stelara : EPAR - Medicine overview (PDF/152.9 KB)

First published: 09/02/2009
Last updated: 06/04/2020
EMA/19731/2020

Available languages (22)

Stelara : EPAR - Risk-management-plan summary (PDF/1.76 MB)

First published: 12/09/2019
Last updated: 17/07/2023

This EPAR was last updated on 17/07/2023

## Authorisation details

| Name |
| --- |
| Stelara |
| Agency product number |
| EMEA/H/C/000958 |

Active substance

Ustekinumab

International non-proprietary name (INN) or common name

ustekinumab

Therapeutic area (MeSH)

- Psoriasis
- Arthritis, Psoriatic
- Crohn Disease
- Colitis, Ulcerative

Anatomical therapeutic chemical (ATC) code

L04AC05

Marketing-authorisation holder

Janssen-Cilag International NV

Revision

44

Date of issue of marketing authorisation valid throughout the European Union

15/01/2009

Contact address

Turnhoutseweg, 30
B-2340 Beerse
Belgium

## Product information

25/05/2023 Stelara - EMEA/H/C/000958 - H/C/000958

Stelara : EPAR - Product information (PDF/2.91 MB)

First published: 23/01/2009
Last updated: 06/07/2023

Available languages (24)

This medicine's product information is available in all **official EU languages**.
Select 'available languages' to access the language you need.

Product information documents contain:

- summary of product characteristics (annex I);
- manufacturing authorisation holder responsible for batch release (annex IIA);
- conditions of the marketing authorisation (annex IIB);
- labelling (annex IIIA);
- package leaflet (annex IIIB).

*You can find product information documents for centrally authorised human medicines on this website. For centrally authorised veterinary medicines authorised or updated from February 2022, see the Veterinary Medicines Information website.*

Stelara : EPAR - All Authorised presentations (PDF/25.73 KB)

First published: 09/02/2009
Last updated: 06/07/2023

Available languages (24)

Stelara : EPAR - Conditions imposed on member states for safe and effective use - Annex IV (PDF/29.2 KB)

First published: 03/03/2009
Last updated: 15/04/2010

Available languages (21)

**Pharmacotherapeutic group**

Immunosuppressants

**Therapeutic indication**

**Crohn's Disease**

Stelara is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies.

**Ulcerative colitis**
STELARA is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis

who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic or have medical contraindications to such therapies.

**Plaque psoriasis**

Stelara is indicated for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate and psoralen ultraviolet A.

**Paediatric plaque psoriasis**

Stelara is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescent patients from the age of 6 years and older, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

**Psoriatic arthritis**

Stelara, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.

## Assessment history

**Changes since initial authorisation of medicine**

Stelara : EPAR - Procedural steps taken and scientific information after authorisation (PDF/364.56 KB)

First published: 17/02/2010
Last updated: 06/07/2023

Stelara-H-C-958-P46-055 : EPAR - Assessment Report (PDF/1.11 MB)

Adopted

First published: 18/01/2023
EMA/12636/2023

Stelara-H-C-PSUSA-00003085-202112 : Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s) (PDF/101.23 KB)

Adopted

First published: 15/11/2022
EMA/884594/2022

Stelara-H-C-PSUSA-00003085-202012 : Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/221.71 KB)

First published: 18/11/2021
EMA/CHMP/684614/2021

Stelara-H-C-958-P46-051 : EPAR - Assessment Report (PDF/1.55 MB)

Adopted

First published: 16/09/2021
EMA/294893/2021

Stelara-H-C-958-II-0073 : EPAR - Assessment Report - Variation (PDF/4.03 MB)

Adopted

First published: 22/01/2020
EMA/12150/2020

Stelara : EPAR - Paediatric investigation plan compliance statement (PDF/129.39 KB)

Adopted

First published: 22/01/2020
EMA/22261/2020

CHMP post-authorisation summary of positive opinion for Stelara (II-73) (PDF/163.37 KB)

Adopted

First published: 13/12/2019
EMA/CHMP/645416/2019

Stelara-H-C-PSUSA-00003085-201812 : Scientific conclusions and grounds for the variation to the terms of the marketing authorisation (PDF/69.25 KB)

First published: 03/10/2019
EMA/523745/2019

Stelara-H-C-958-II-0071 : EPAR - Assessment Report - Variation (PDF/10.28 MB)

Adopted

First published: 12/09/2019
EMA/450688/2019

CHMP post-authorisation summary of positive opinion for Stelara - II/0071 (PDF/82.52 KB)

Adopted

First published: 26/07/2019
EMA/CHMP/408535/2019

Stelara-H-C-000958-X-0049-G : EPAR - Assessment Report - Extension (PDF/7.58 MB)

Adopted

First published: 25/11/2016
Last updated: 08/02/2017
EMA/657144/2016

CHMP post-authorisation summary of positive opinion for Stelara (PDF/83.49 KB)

Adopted

First published: 16/09/2016
Last updated: 16/09/2016
EMA/CHMP/582037/2016

Stelara-H-C-958-II-0042 : EPAR - Assessment Report - Variation (PDF/6.14 MB)

Adopted

First published: 13/08/2015
Last updated: 13/08/2015
EMA/404738/2015

CHMP post-authorisation summary of positive opinion for Stelara (PDF/85.38 KB)

Adopted

First published: 22/05/2015
Last updated: 22/05/2015
EMA/CHMP/333057/2015

Stelara-H-C-958-II-0037 : EPAR - Assessment Report - Variation (PDF/3.21 MB)

Adopted

First published: 17/03/2014
Last updated: 17/03/2014
EMA/CHMP/129351/2014

CHMP post-authorisation summary of positive opinion for Stelara (PDF/68.68 KB)

Adopted

First published: 24/01/2014
Last updated: 24/01/2014
EMA/CHMP/20129/2014

Stelara-H-C-958-II-0029 : EPAR - Assessment Report - Variation (PDF/2.85 MB)

Adopted

First published: 26/09/2013
Last updated: 26/09/2013
EMA/CHMP/431551/2013

**Initial marketing-authorisation documents**

Stelara : EPAR - Public assessment report (PDF/888.98 KB)

First published: 09/02/2009
Last updated: 09/02/2009

CHMP summary of positive opinion for Stelara (PDF/79.81 KB)

First published: 20/11/2008
Last updated: 20/11/2008
EMEA/CHMP/582270/2008

## News

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 24 - 27 October 2022
  28/10/2022
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019
  13/12/2019
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2019
  26/07/2019
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 September 2016 (corrected)
  21/09/2016
- 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) 20-23 January 2014
  24/01/2014
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 July 2013
  26/07/2013

- Clinical data (X/0049)

## Related content

- Stelara: Paediatric investigation plan
- Stelara: Paediatric investigation plan
- Stelara: Paediatric investigation plan
- Stelara: Paediatric investigation plan
- Stelara: Paediatric investigation plan

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