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Tremfya (*guselkumab*)

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

What is Tremfya and what is it used for?

Tremfya is a medicine used to treat:

- moderate to severe plaque psoriasis (a disease causing red, scaly skin patches) in adults and children from 6 years of age for whom treatment with medicines given by mouth or by injection is appropriate;
- psoriatic arthritis (scaly skin patches with joint inflammation) in adults, alone or with another medicine called methotrexate. It is used when medicines to treat the underlying inflammation (disease-modifying medicines) have not worked well enough or have caused unacceptable side effects;
- ulcerative colitis (inflammation of the large intestine causing ulceration and bleeding) in adults. It is used to treat moderately- to severely-active disease when other treatments have not worked well enough, have stopped working, or have caused unacceptable side effects;
- Crohn's disease (an inflammatory disease affecting the gut) in adults. It is used to treat moderately to severely active disease when other treatments have not worked well enough, have stopped working or have caused unacceptable side effects.

Tremfya contains the active substance guselkumab.

How is Tremfya used?

Tremfya can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating the conditions for which Tremfya is used.

For patients with plaque psoriasis and psoriatic arthritis, Tremfya is available as an injection in pre-filled syringes or pens. It is injected under the skin in an area that is clear of psoriasis. After the first injection, treatment is repeated after 4 weeks and every 8 weeks thereafter (maintenance treatment). For patients with psoriatic arthritis who have a high risk of joint damage, the doctor may decide that Tremfya can be injected every 4 weeks instead of every 8 weeks during the maintenance phase.

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

For patients with ulcerative colitis and Crohn's disease, Tremfya is available as a solution for infusion (drip) into a vein and as an injection under the skin using pre-filled syringes or pens. Treatment starts with an infusion into a vein given every 4 weeks for 3 times (induction treatment). The induction treatment may also be given as an injection under the skin with the same schedule as for treatment given by infusion. The patient then begins maintenance treatment, which is given as an injection under the skin every 8 weeks or every 4 weeks thereafter, depending on how well treatment worked during the induction phase.

The doctor may stop treatment if the patient's condition does not improve after 16 weeks for adults with plaque psoriasis, or 24 weeks for children with plaque psoriasis and adults with psoriatic arthritis, ulcerative colitis and Crohn's disease.

After training, adult patients or carers may inject Tremfya themselves if the doctor considers it appropriate.

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

How does Tremfya work?

The active substance in Tremfya, guselkumab, is a monoclonal antibody (a type of protein) which is designed to attach to interleukin-23 (IL-23) and block its activity. IL-23 is a protein that controls the growth and maturation of some types of T cells. These T cells, which are part of the body's immune system (the body's natural defences), are involved in causing inflammation that is linked to plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease. By blocking the action of IL-23, guselkumab reduces inflammation and other symptoms of these diseases.

What benefits of Tremfya have been shown in studies?

Plaque psoriasis

Three main studies involving 2,700 adults found Tremfya effective for treating moderate to severe plaque psoriasis in patients for whom treatments applied to the skin did not work well enough. A main measure of effectiveness was a reduction of at least 90% in PASI scores. PASI is a measure of disease severity and area of skin affected.

The first two studies compared Tremfya with adalimumab (another medicine used for treating psoriasis) and placebo (a dummy treatment). After 16 weeks, about 71% of patients (588 out of 825) receiving Tremfya had a reduction of at least 90% in PASI scores, compared with 48% (282 out of 582) of those receiving adalimumab and under 3% (11 out of 422) of those receiving placebo. Improvement in psoriasis symptoms was maintained beyond 48 weeks with Tremfya treatment.

The third study involved 871 patients who were treated with ustekinumab (another medicine used for treating psoriasis). Patients whose psoriasis did not improve sufficiently after 16 weeks either received Tremfya or continued treatment with ustekinumab for at least 24 weeks. During this period, symptoms of psoriasis improved to a greater extent in patients receiving Tremfya than in those remaining on ustekinumab.

An additional study involving 92 adolescents and children from 6 years of age showed that Tremfya is also effective for treating moderate to severe plaque psoriasis in this age group. After 16 weeks, around 76% (31 out of 41) of patients receiving Tremfya had a reduction of at least 75% in PASI scores, compared with 20% (5 out of 25) of those receiving placebo. In addition, 66% (27 out of 41)

of children given Tremfya had skin that was clear or almost clear of psoriasis, compared with 16% (4 out of 25) of children given placebo.

Psoriatic arthritis

A study looked at the effect of Tremfya in 381 patients with psoriatic arthritis for whom standard treatments did not work. Around 52% of those treated with Tremfya every 8 weeks and 59% of those treated with Tremfya every 4 weeks had a 20% improvement in a symptom score (called ACR20) after 24 weeks. This compared with 22% of those receiving placebo.

In another study, involving 739 patients, 64% of patients receiving Tremfya every 8 or 4 weeks had a 20% improvement in symptom score after 24 weeks, compared with 33% of those receiving placebo.

Ulcerative colitis

Two main studies found that Tremfya was effective at treating adults with moderately to severely active ulcerative colitis, for whom other treatments did not work well enough or caused unacceptable side effects.

In the first study, 23% (95 out of 421) of those who received Tremfya infusions over 8 weeks of induction treatment had clinical remission (a decrease in or disappearance of signs and symptoms of the disease) after 12 weeks, compared with 8% (22 out of 280) of patients who received placebo (a dummy treatment). Clinical remission was evaluated by the modified Mayo score, which measures changes in stool frequency, rectal bleeding (bleeding from the last several inches of the large intestine closest to the anus) and endoscopic subscore (measure of inflammation in the intestines based on a procedure that uses a tube with a camera to look inside the body).

A second study involved patients from the first main study and another supporting study who had responded to induction treatment with Tremfya. The study looked at the effectiveness of maintenance treatment given by injection under the skin every 4 weeks at a higher dose or every 8 weeks at a lower dose. After 44 weeks, 45% (85 out of 188) of patients receiving the lower dose of Tremfya and 50% (95 out of 190) of patients receiving the higher dose of Tremfya were in clinical remission, compared with 19% (36 out of 190) of those who received placebo.

Crohn's disease

Three main studies involving around 1,400 patients found that Tremfya was effective at treating adults with moderately to severely active Crohn's disease, for whom other treatments did not work well enough or caused unacceptable side effects. In the first 2 studies patients received induction treatment with Tremfya by infusion, while in the third study the induction treatment was given as an injection under the skin. In all 3 studies, maintenance treatment was given by injection under the skin. The main measures of effectiveness were clinical remission (a decrease in or disappearance of signs and symptoms of the disease) and endoscopic response (improvement in inflammation in the intestines based on a procedure that uses a tube with a camera to look inside the body). Clinical remission was evaluated using the CDAI (Crohn's disease activity index) score which measures different parameters including stool frequency, abdominal (belly) pain, and general well-being. Endoscopic response was based on at least a 50% improvement in a score called SES-CD (simple endoscopic score for Crohn's disease) or on an SES-CD score of 2 or below.

In the first study, clinical remission was achieved after 12 weeks of treatment in 47% (136 out of 289) of the patients receiving Tremfya compared with 22% (17 out of 76) of those who received placebo. Endoscopic response was achieved after 12 weeks of treatment in 38% (109 out of 289) of the patients receiving Tremfya compared with 11% (8 out of 76) of those receiving placebo.

In the second study clinical remission was achieved after 12 weeks of treatment with Tremfya in 47% (138 out of 293) of patients compared with 15% (11 out of 72) of those receiving placebo. Endoscopic response was achieved after 12 weeks of treatment in 36% (106 out of 293) of the patients receiving Tremfya compared with 14% (10 out of 72) of those who received placebo.

In the third study clinical remission was achieved after 12 weeks of treatment with Tremfya in 56% (129 out of 230) of patients compared with 21% (25 out of 117) of those receiving placebo. Endoscopic response was achieved after 12 weeks of treatment in 41% (95 out of 230) of the patients receiving Tremfya compared with 21% (25 out of 117) of those who received placebo.

What are the risks associated with Tremfya?

For the full list of side effects and restrictions with Tremfya, see the package leaflet.

The most common side effects with Tremfya (which may affect more than 1 in 10 people with psoriasis, psoriatic arthritis and Crohn's disease, and up to 1 in 10 people with ulcerative colitis) include infections in the nose and throat.

Tremfya must not be used in patients who have an active infection that the doctor considers important.

Why is Tremfya authorised in the EU?

The European Medicines Agency decided that Tremfya's benefits are greater than its risks in the treatment of moderate and severe plaque psoriasis, psoriatic arthritis, ulcerative colitis and Crohn's disease and that it can be authorised for use in the EU.

The Agency considered that Tremfya is effective and longer-term studies for plaque psoriasis have shown that it remains effective with continued use. Tremfya improved physical function and quality of life in patients with psoriatic arthritis. Long-term safety data have shown that it has few side effects. For patients with moderately to severely active ulcerative colitis and Crohn's disease, the Agency considered treatment with Tremfya to be effective with a safety profile that is consistent with that already known for the medicine. After the induction phase, patients are likely to continue treatment with Tremfya because it can be injected every 4 to 8 weeks and adult patients or carers can inject it themselves, making it convenient to use.

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

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

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

Other information about Tremfya

Tremfya received a marketing authorisation valid throughout the EU on 10 November 2017.

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

This overview was last updated in 12-2025.