EMA/644237/2022
EMEA/H/C/004271

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) when treatments applied to the skin are not suitable.

It is also used to treat psoriatic arthritis (scaly skin patches with joint inflammation) alone or with another medicine called methotrexate. For psoriatic arthritis, Tremfya is used when medicines to treat the underlying inflammation (disease-modifying medicines) have not worked well enough or when the patient cannot take these medicines.

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.

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. The recommended dose is 100 mg, followed by a further dose after 4 weeks and then 100 mg every 8 weeks. For patients with psoriatic arthritis who have a high risk of joint damage, the doctor may decide that it can be injected every 4 weeks. The doctor may stop treatment if the condition does not improve after 16 or 24 weeks.

After training, patients 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 and block its activity. Interleukin 23 is a messenger substance 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

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 60
An agency of the European Union

plaque psoriasis and psoriatic arthritis. By blocking the action of interleukin 23, guselkumab reduces inflammation and other symptoms of the disease.

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) 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.

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.

What are the risks associated with Tremfya?

The most common side effects with Tremfya (which may affect more than 1 in 10 people) are infections in the nose and throat.

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

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

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 and psoriatic arthritis 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. It improved physical function and quality of life in patients with psoriatic arthritis. Long-term safety data have shown that it has few side effects. Patients are likely to continue treatment with Tremfya because it can be injected every 8 weeks (after the first 4 weeks) and patients 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 11-2020.