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Usgena (*ustekinumab*)

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

What is Usgena and what is it used for?

Usgena 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 from 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). Usgena 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.

Usgena contains the active substance ustekinumab and is a biological medicine. It is a 'biosimilar medicine'; this means that Usgena is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Usgena is Stelara. For more information on biosimilar medicines, see here.

How is Usgena used?

Usgena 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 Usgena is used for.

In plaque psoriasis and psoriatic arthritis, Usgena is injected under the skin. The first injection is followed by another injection 4 weeks later. After that, one injection is given every 12 weeks.

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In Crohn's disease and ulcerative colitis, Usgena treatment is started as an infusion (drip) into a vein lasting at least 1 hour. Eight weeks after the first infusion, Usgena is given as an injection under the skin. Patients then continue with Usgena injected under the skin every 8 or 12 weeks, depending on how well the treatment is working.

Patients or their caregivers may inject Usgena under the skin once they have been trained, if their doctor thinks that this is appropriate.

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

How does Usgena work?

The active substance in Usgena, 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 two 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 Usgena have been shown in studies?

Laboratory studies comparing Usgena with Stelara have shown that the active substance in Usgena is highly similar to that in Stelara in terms of structure, purity and biological activity. Studies have also shown that giving Usgena produces similar levels of the active substance in the body to those seen with Stelara.

In addition, a study involving 581 adults with moderate to severe plaque psoriasis showed that Usgena was as effective as Stelara at improving symptoms of the disease. After 12 weeks of treatment, adults given either Usgena or Stelara had on average an 87% improvement in their PASI scores (a measure of how severe the disease is and how much of the skin is affected).

Because Usgena is a biosimilar medicine, the studies on the effectiveness of ustekinumab carried out with Stelara do not all need to be repeated for Usgena.

What are the risks associated with Usgena?

The safety of Usgena has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine Stelara.

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

The most common side effects with ustekinumab (seen in more than 1 in 20 people during clinical trials) include headache and nasopharyngitis (inflammation of the nose and throat). The most serious side effect reported with ustekinumab (which may affect up to 1 in 1,000 people) is serious hypersensitivity (allergic reactions) including anaphylaxis (sudden, severe allergic reaction).

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

Why is Usgena authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Usgena has a highly similar structure, purity and biological activity to Stelara and is

distributed in the body in the same way. In addition, studies in adults with plaque psoriasis have shown that Usgena and Stelara are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Usgena will have the same effects as Stelara in its authorised uses. Therefore, the Agency's view was that, as for Stelara, the benefits of Usgena outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Usgena

Usgena received a marketing authorisation valid throughout the EU on 17 November 2025.

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

This overview was last updated in 11-2025.