EMA/332657/2017
EMEA/H/C/003959

**EPAR summary for the public**

# Kyntheum

brodalumab

This is a summary of the European public assessment report (EPAR) for Kyntheum. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Kyntheum.

For practical information about using Kyntheum, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Kyntheum and what is it used for?

Kyntheum is a medicine used to treat plaque psoriasis, a disease causing red, scaly patches on the skin. It is used in adults whose disease is moderate to severe and who require systemic treatment (treatment with medicines given by mouth or by injection).

Kyntheum contains the active substance brodalumab.

## How is Kyntheum used?

Kyntheum can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating psoriasis.

Kyntheum is available as a solution for injection in pre-filled syringes. It is given as an injection under the skin. The recommended dose is 210 mg given once a week for the first 3 weeks and then every 2 weeks. The doctor may decide to stop treatment if the condition does not improve after 12 to 16 weeks.

After training, patients may inject Kyntheum if their doctor considers it appropriate. For further information, see the package leaflet.

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## How does Kyntheum work?

The active substance in Kyntheum, brodalumab, is a monoclonal antibody, a protein designed to block the activity of certain substances called interleukins 17 (A, F and A/F), which are messengers in the body's immune system (the body's natural defences). Interleukins 17 are involved in the process of inflammation that causes plaque psoriasis. By blocking the action of interleukin 17 substances, brodalumab reduces the inflammation and symptoms associated with the disease.

## What benefits of Kyntheum have been shown in studies?

Kyntheum has been shown to be effective at treating plaque psoriasis in 3 main studies involving over 4,300 patients who required systemic treatment. Plaque psoriasis improved to a greater extent in patients treated with Kyntheum than with placebo (a dummy treatment) or with ustekinumab (another medicine for psoriasis that targets interleukin molecules).

Looking at the results of the 3 studies together, 85% of patients treated with Kyntheum obtained a 75% reduction in PASI scores (a measure of disease severity and area of skin affected) after 12 weeks. This compares with 6% of those given placebo and with 70% of patients given ustekinumab. Also, 79% of patients given Kyntheum had clear or nearly clear skin after 12 weeks, compared with 3% of patients given placebo and 70% of patients given ustekinumab.

Data from one study also showed that the benefits of treatment with Kyntheum were maintained when treatment was continued for one year.

## What are the risks associated with Kyntheum?

The most common side effects with Kyntheum (which may affect more than 1 in 100 people) are joint pain, headache, tiredness, diarrhoea and oropharyngeal pain (pain in the mouth and throat).

Kyntheum must not be given to patients who have potentially serious infections such as tuberculosis and to patients with active Crohn’s disease (an inflammatory disease affecting the gut). There have been some reports of suicidal behaviour in patients taking the medicine. Although there is no evidence of a link to the medicine, the decision to start Kyntheum in patients who have had suicidal behaviour in the past or suffered from depression or anxiety should be made after carefully looking at all the risks and benefits for that patient. Kyntheum should be stopped in patients who show new symptoms of depression or anxiety or in case they worsen.

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

## Why is Kyntheum approved?

Although there have been recent advances in the treatment of plaque psoriasis, there remains a need for new treatment options. Studies have shown that Kyntheum was highly effective at clearing the skin and the positive effects were maintained with continued use. Side effects are similar to those of other medicines that target interleukin molecules.

The European Medicines Agency therefore decided that Kyntheum’s benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

## Other information about Kyntheum

The European Commission granted a marketing authorisation valid throughout the European Union for Kyntheum on 17 July 2017.

The full EPAR for Kyntheum can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Kyntheum, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2017.