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Sotyktu (*deucravacitinib*)

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

What is Sotyktu and what is it used for?

Sotyktu is a medicine for treating adults with moderate to severe plaque psoriasis (an inflammatory disease causing red, scaly patches on the skin) who are eligible for systemic therapy (treatment with a medicine given by mouth or by injection).

Sotyktu contains the active substance deucravacitinib.

How is Sotyktu used?

Sotyktu can only be obtained with a prescription. Treatment should be started by a doctor experienced in the diagnosis and treatment of psoriasis.

Sotyktu is available as tablets, which the patient takes once a day. The doctor should evaluate the effect of the treatment regularly and may stop treatment if the condition does not improve after 24 weeks.

For more information about using Sotyktu, including dose recommendations, see the package leaflet or contact your doctor or pharmacist.

How does Sotyktu work?

The active substance in Sotyktu, deucravacitinib, blocks the action of an enzyme inside cells called tyrosine kinase 2 (TYK2) which belongs to the Janus kinases (JAK) family of proteins. This enzyme plays a role in triggering the production of substances known as cytokines, which are involved in the inflammation and other processes that cause psoriasis. By blocking the action of TYK2, deucravacitinib prevents the production of cytokines, thereby reducing inflammation and improving the symptoms of plaque psoriasis.

What benefits of Sotyktu have been shown in studies?

Two main studies involving 1,686 patients with moderate to severe plaque psoriasis compared Sotyktu with placebo (a dummy treatment) and apremilast, another systemic therapy for plaque psoriasis. The studies looked at an improvement of patients' symptoms after 16 weeks of treatment.

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

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Around 55% of patients treated with Sotyktu had a reduction of at least 75% in their PASI score (a measure of the severity and extent of skin lesions) compared with around 38% of those treated with apremilast and around 11% of those who received placebo.

Additionally, around 51% of patients treated with Sotyktu achieved a sPGA score (a measure of the severity and extent of skin lesions) of 0 or 1 (where 0 and 1 refer to skin clear or almost clear, respectively) and had a reduction of 2 points or more in their sPGA score. Around 33% of those treated with apremilast and around 8% in those who received placebo had these results.

Improvement of symptoms were maintained after 52 weeks of treatment with Sotyktu.

What are the risks associated with Sotyktu?

The most common side effect with Sotyktu (which may affect more than 1 in 10 people) is upper respiratory infection (nose and throat infection). For the full list of side effects of Sotyktu, see the package leaflet.

Patients who have an important or long-term infection, or an infection that keeps coming back, must not take this medicine. For the full list of restrictions, see the package leaflet.

Why is Sotyktu authorised in the EU?

Studies show that Sotyktu is effective at reducing the symptoms of moderate to severe plaque psoriasis. Side effects are mild to moderate and manageable. Sotyktu provides an additional treatment option for patients who have not yet been treated with systemic therapy and those who do not benefit from other systemic therapies. Therefore, the European Medicines Agency decided that Sotyktu's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Sotyktu

Sotyktu received a marketing authorisation valid throughout the EU on 24 March 2023.

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

This overview was last updated in 03-2023.