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Withdrawal of application for the marketing authorisation of Veblocema (infliximab)

Celltrion Healthcare Hungary Ktf. withdrew its application for a marketing authorisation of Veblocema for the treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis.

The company withdrew the application on 8 May 2026.

What is Veblocema and what was it intended to be used for?

Veblocema was developed as a medicine for the treatment of rheumatoid arthritis, Crohn's disease and ulcerative colitis in adults.

Veblocema contains the active substance infliximab and was to be available as pre-filled syringes and pre-filled pens containing a solution for injection.

How does Veblocema work?

The active substance in Veblocema, infliximab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Infliximab attaches to a chemical messenger called tumour necrosis factor alpha (TNF-alpha). This messenger is involved in causing inflammation and is found at high levels in patients with rheumatoid arthritis, Crohn's disease and ulcerative colitis. By blocking TNF-alpha, infliximab improves the inflammation and other symptoms of these diseases.

What did the company present to support its application?

The company submitted the results of three main studies in patients with rheumatoid arthritis, Crohn's disease and ulcerative colitis.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn while the European Medicines Agency was still evaluating the initial information from the company.

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

What did the Agency recommend at that time?

As the Agency was still evaluating the initial information from the company, it had not yet made any recommendations.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it was withdrawing due to a change in their business strategy.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there no ongoing clinical trials with Veblocema.