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Exdensur (*depemokimab*)

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

What is Exdensur and what is it used for?

Exdensur is a medicine used to treat:

- severe asthma in people aged 12 years and above whose asthma is not properly controlled with corticosteroids taken by inhalation plus another asthma medicine. It is only for use in people with a type of inflammation of the airways called 'type 2 inflammation', based on high levels of eosinophils (a type of white blood cell involved in inflammation). It is used in addition to maintenance treatment.
- severe inflammation of the nose and sinuses with growths (polyps) obstructing the airways in the nose (chronic rhinosinusitis with nasal polyps). It is used in adults in addition to a corticosteroid given into the nose when corticosteroids given by mouth or injection, with or without surgery, have not worked well enough.

Exdensur contains the active substance depemokimab.

How is Exdensur used?

Exdensur can only be obtained with a prescription and should be prescribed by a doctor experienced in diagnosing and treating asthma or chronic rhinosinusitis with nasal polyps.

The medicine is available in pre-filled pens and syringes. It is given as an injection under the skin, usually in the thigh or abdomen (belly), once every 6 months. Patients or their carers may inject the medicine themselves if their doctor or nurse considers it appropriate, and once they have been trained to do so.

The medicine is for long-term use and the need to continue taking the medicine should be assessed by the doctor regularly.

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

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How does Exdensur work?

Patients with some types of asthma and chronic rhinosinusitis with nasal polyps produce too many eosinophils. The production and survival of eosinophils is stimulated by a protein called interleukin-5 (IL-5). The active substance in Exdensur, depemokimab, is a monoclonal antibody (a type of protein) designed to attach to IL-5. By attaching to this protein, depemokimab blocks its activity, thereby reducing the number of eosinophils. This helps to reduce inflammation, which leads to an improvement in symptoms.

What benefits of Exdensur have been shown in studies?

Asthma

Two main studies found that Exdensur was effective at reducing the number of severe exacerbations (attacks) of asthma with type 2 inflammation in people aged 12 years and above whose asthma was not adequately controlled with standard treatment. The studies involved a total of 792 people, including 30 adolescents (aged 12 to 17), who received either Exdensur or a placebo (dummy treatment) in addition to standard treatment. After 52 weeks, the average number of severe attacks per year was 0.5 in people who received Exdensur and 1.1 in those who received placebo.

The company also provided supportive data from these studies on the effect of Exdensur on health-related quality of life reported by patients (based on scores from 2 questionnaires (SGRQ and ACQ-5) that assess how asthma affects a person's daily life) and on lung function (based on FEV1, the maximum volume of air a person can breathe out in one second). After 52 weeks, there was no difference between patients treated with Exdensur and those who received placebo in either the SGRQ and ACQ-5 scores or FEV1.

Chronic rhinosinusitis with nasal polyps

Two main studies found Exdensur to be effective in treating adults with severe chronic rhinosinusitis with nasal polyps. The studies involved a total of 540 people who received either Exdensur or placebo in addition to standard treatment. The main measure of effectiveness was a combined improvement in the size of the polyps and in nasal obstruction. Polyp size was measured using the nasal polyp score (ranging from 0 to 8; scored per nostril from 0 (no polyps) to 4 (large polyps)). Nasal obstruction was measured using the verbal response scale (VRS) symptom score, which ranged from 0 (no symptoms) to 3 (severe symptoms).

After 52 weeks, the average nasal polyp score improved by 0.5 points in people who received Exdensur compared with a worsening of 0.1 points in those who received placebo. Nasal obstruction improved by an average of 0.8 points with Exdensur compared with an average improvement of 0.5 points with placebo.

What are the risks associated with Exdensur?

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

The most common side effects with Exdensur (which may affect up to 1 in 10 people) are reactions at the site of injection, including pain, redness, swelling and itching.

Why is Exdensur authorised in the EU?

Exdensur is effective at reducing the number of severe attacks of asthma with type 2 inflammation when used in addition to other treatment. However, treatment with Exdensur did not show an

improvement in health-related quality of life or lung function in people with this form of asthma. Exdensur is also effective at treating severe chronic rhinosinusitis with nasal polyps.

The European Medicines Agency noted that Exdensur is only given once every 6 months, which may make it easier for patients to keep to their treatment schedule. In terms of safety, Exdensur was well tolerated and side effects were generally mild. The Agency therefore decided that Exdensur's benefits are greater than its risks and that it can be authorised for use in the EU.

During the evaluation, the Agency also consulted the European Respiratory Society, who provided the healthcare professionals' perspective on the diseases and on the treatments currently available.

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

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

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

Other information about Exdensur

Exdensur received a marketing authorisation valid throughout the EU on 12 February 2026.

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

This overview was last updated in 02-2026.