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**EPAR summary for the public**

# Nucala

mepolizumab

This is a summary of the European public assessment report (EPAR) for Nucala. 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 Nucala.

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

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

Nucala is an asthma medicine used to treat adults with a particular type of asthma called eosinophilic asthma. It is used with other medicines in patients whose asthma is severe and not well controlled with previous treatments.

Nucala contains the active substance mepolizumab.

## How is Nucala used?

Nucala should be prescribed by a doctor experienced in identifying and treating severe eosinophilic asthma, and can only be obtained with a prescription. It is available as a powder to make up a solution for injection, and is injected by a healthcare professional under the skin of the upper arm, thigh or abdomen (belly) once every 4 weeks. The recommended dose is 100 mg. Nucala is intended for long-term treatment.

## How does Nucala work?

In eosinophilic asthma, symptoms are associated with having too many of a type of white blood cell called eosinophils in the blood and in phlegm in the lungs. The active substance in Nucala, mepolizumab, is a type of protein called a monoclonal antibody, which attaches to a specific substance in the body. Mepolizumab attaches to a substance called interleukin-5 which encourages the production and survival of eosinophils. By attaching to interleukin-5, mepolizumab blocks its action and thereby

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reduces the numbers of eosinophils. This helps to reduce inflammation, resulting in a reduction in asthma attacks and improvement of symptoms.

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

The benefits of Nucala in severe eosinophilic asthma that is not well controlled by previous treatment have been shown in three main studies, in which it was compared with a placebo (dummy) injection. The first study involved 616 adults and adolescents given Nucala every 4 weeks for a year, in addition to their regular asthma medicines. The second study involved 576 adults and adolescents given Nucala every 4 weeks for 28 weeks. The main measure of effectiveness in these studies was the number of severe attacks (exacerbations) of asthma that occurred during treatment, which was reduced by about half in patients given Nucala.

The third study involved 135 patients with eosinophilic asthma severe enough to need regular treatment by mouth with corticosteroids (potent anti-inflammatory medicines such as prednisone and prednisolone), and the main measure of effectiveness was how much the corticosteroid dose could be reduced using Nucala for 24 weeks compared with placebo. Over half (37 of 69) of the patients given Nucala were able to reduce their daily corticosteroid dose by more than 50% to a dose of 5 mg or less, and 10 of them were able to stop corticosteroids altogether, compared with about a third of those given placebo (22 of 66, of whom 5 were able to stop corticosteroids).

## What are the risks associated with Nucala?

The most common side effect with Nucala (which may affect more than 1 in 10 people) is headache; reactions at the site of injection and back pain are also common, affecting up to 1 patient in 10. For the full list of all side effects and restrictions with Nucala, see the package leaflet.

## Why is Nucala approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Nucala's benefits are greater than its risks and recommended that it be approved for use in the EU. The reduction in severe asthma attacks and consequent need for hospital treatment was considered important and outweighed the low risk of side effects, since the medicine's safety profile raised no major concerns. In addition, a reduction in corticosteroid dose of 5 mg daily, although modest, was considered clinically relevant, given the complications of long-term corticosteroid treatment.

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

A risk management plan has been developed to ensure that Nucala is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Nucala, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

## Other information about Nucala

The European Commission granted a marketing authorisation valid throughout the European Union for Nucala on 2 December 2015.

The full EPAR and risk management plan summary for Nucala 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 Nucala, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2015.