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Nucala (*mepolizumab*)

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

What is Nucala and what is it used for?

Nucala is an asthma medicine used to treat patients aged 6 years and above 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 can only be obtained with a prescription and should be prescribed by a doctor experienced in identifying and treating severe eosinophilic asthma. The medicine is given by injection under the skin of the upper arm, thigh or abdomen (belly) once every 4 weeks. The recommended dose is 100 mg in patients aged 12 years and above, and 40 mg in patients aged 6 to 11 years. Nucala is intended for long-term treatment.

Nucala is available as a solution in a prefilled pen or syringe or as a powder that comes in a vial and is made up into an injection. The patient and carer can use Nucala prefilled pen or syringe themselves once they have been trained, whereas the vial is only for use by a healthcare professional. For more information about using Nucala, see the package leaflet or contact your doctor or pharmacist.

How does Nucala work?

In eosinophilic asthma, symptoms are associated with having too many eosinophils (a type of white blood cell) 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 reduces the numbers of eosinophils. This helps to reduce inflammation, resulting in a reduction in asthma attacks and improvement of symptoms.

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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 mostly adult 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).

An additional study was carried out in children aged 6 years to 11 years which showed that a dose of 40 mg Nucala given under the skin produced comparable levels of active substance in the body to those seen with standard doses in adults. The reduction in eosinophil levels in the blood achieved in children was also comparable with that seen with standard doses in adults.

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 common, affecting up to 1 patient in 10. For the full list of side effects and restrictions with Nucala, see the package leaflet.

Why is Nucala authorised in the EU?

The European Medicines Agency decided that Nucala's benefits are greater than its risks and it can be authorised for use in the EU. In adults the reduction seen in severe asthma attacks and consequent need for hospital treatment was considered important and outweighed the low risk of side effects. In addition, a reduction in corticosteroid dose was considered clinically relevant, given the potential complications of long-term corticosteroid treatment. In children, eosinophilic asthma is rare and the data available are therefore limited. The Agency concluded that the data available indicate that Nucala acts in a similar way in adults and children and the results in adults therefore also apply to children with eosinophilic asthma.

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

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

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

Other information about Nucala

Nucala received a marketing authorisation valid throughout the EU on 2 December 2015.

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

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