



EMA/12897/2021 Rev. 1

Update of 1 March 2021:

The shortage affecting Nucala has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

27 January 2021

Shortage of Nucala (mepolizumab) pre-filled pen	
Indication	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.
Reason for shortage	<p>A manufacturing issue with the delivery system of the Nucala pre-filled pen has led to a shortage with this presentation. Nucala pre-filled syringe and lyophilised powder for reconstitution are not affected. The manufacturing issue has now been corrected and normal production has resumed. However, it will take time before normal supplies can resume and supply problems are expected to last until mid February 2021.</p> <p>Nucala pre-filled pens already supplied are expected to function normally (as long as they are not dropped during transport or before use).</p>
Member States affected¹	Shortages are expected to occur in Cyprus and Poland.
Information for healthcare professionals	<ul style="list-style-type: none">• A manufacturing issue with the Nucala pre-filled pen has led to a shortage of this formulation. The other presentations of Nucala (pre-filled syringe and lyophilised for reconstitution versions) are not affected.• Patients who currently use the Nucala pre-filled pen should be switched during the shortage to an alternative Nucala presentation or alternative treatment as appropriate. When choosing an alternative Nucala presentation for your patients, the following should be

¹ This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the national competent authority.



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	<p>considered:</p> <ul style="list-style-type: none">- For patients who self-administer at home or where a caregiver administers at home, the pre-filled syringe is the most suitable alternative; this may require extra training on administration technique.- For patients who are given their dose by a healthcare professional either at home or in the clinic, the pre-filled syringe or the lyophilised powder for reconstitution presentations can be used.- In some circumstances, patients may have to attend clinic for administration of the alternative. <ul style="list-style-type: none">• Additional advice may be available from the competent authority in your country.• In addition, healthcare professionals in Cyprus and Poland will receive a letter regarding this issue. The letter (DHPC) can also be found on the EMA website.
Information for patients	<ul style="list-style-type: none">• A manufacturing issue with the Nucala pre-filled pen has led to a shortage with this formulation in Cyprus and Poland. The other presentations of Nucala (pre-filled syringe and lyophilised for reconstitution versions) are not affected.• If you live in Cyprus or Poland and currently use the Nucala pre-filled pen your doctor may need to prescribe during the shortage an alternative Nucala presentation or other treatment as appropriate.• Your doctor may prescribe Nucala pre-filled syringe for you. If you or your caregiver currently inject the medicine at home, you may receive extra training on how to use the pre-filled syringe.• Your doctor may also prescribe Nucala lyophilised powder for reconstitution, which will have to be made up and given by a healthcare professional. You may therefore have to attend clinic for administration of this presentation.• If you have any questions you should speak to their doctor or pharmacist.• Additional advice may be available from the competent authority in your country.