

## **Direct Healthcare Professional Communication**

### **Shortage of Nucala (mepolizumab) Pre-Filled Pen (EU/1/15/1043/003, EU/1/15/1043/004)**

Dear Healthcare Professional,

GlaxoSmithKline Trading Services in agreement with the European Medicines Agency and the <National Competent Authority> would like to inform you of the following:

#### ***Summary***

- **A manufacturing issue with the delivery system of the Nucala Pre-Filled Pen has led to a shortage which is expected to last until (*market specific date for resolution*). The other presentations of Nucala (pre-filled syringe and lyophilised powder for reconstitution versions) are not affected.**
- **Patients who use the Nucala Pre-Filled Pen should be switched to an alternative Nucala presentation or alternative treatment as deemed appropriate.**
- **If you choose an alternative Nucala presentation for your patients, the following should be considered:**
  - **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.**

#### ***Background on the shortage***

This shortage of Nucala Pre-Filled Pen has been caused by a manufacturing issue. GSK found that some Nucala Pre-filled Pen devices were incorrectly assembled as the syringe holders were not inserted far enough to engage the clip that holds them in position. This manufacturing issue has now been corrected and normal production has resumed.

#### **Call for Reporting**

Any product defects or adverse events occurring in patients receiving Nucala should be reported to (*market specific AE statement*). Please remember to provide details of the product name and batch number when reporting.

**Further information / company contact point**

For up-to-date advice and further information, please contact your local GSK Nucala team on (*add GSK market specific contact details*).

Alternatively, for medical information enquiries please email (*add market specific information*) or call (*add market specific information*).

Yours sincerely,

(*Market Medical Contact / Country Medical Director*)

## Communication Plan for Direct Healthcare Professional Communication

DHPC COMMUNICATION PLAN	
<b>Medicinal product(s)/active substance(s)</b>	Nucala 100 mg solution for injection in pre-filled pen (mepolizumab)
<b>Marketing authorisation holder(s)</b>	GlaxoSmithKline Trading Services
<b>Purpose of the communication</b>	The purpose of the communication is to notify HCPs of possible patient level stock outs of Nucala pre-filled pen only. This shortage has been caused by a manufacturing issue. This manufacturing issue has now been corrected and normal production has resumed.
<b>DHPC recipients</b>	<ul style="list-style-type: none"> <li>Specialists who prescribe the Nucala pre-filled pen</li> <li>Specialist pharmacies that stock Nucala pre-filled pen</li> </ul>
<b>Member States where the DHPC will be distributed</b>	<p>Cyprus, France* and Poland</p> <p>*Potentially out of stock early February 2021, DHCP will be disseminated at this time if required</p>
Timetable	
<b>DHPC and communication plan (in English) agreed by CHMP/CMDh</b>	18 January 2021
<b>Submission of translated DHPCs to the national competent authorities for review</b>	19 January 2021
<b>Agreement of translations by national competent authorities</b>	23 January 2021
<b>Dissemination of DHPC</b>	Commencing 23 January 2021