EMA/181544/2021 Rev. 1

Update of 4 May 2021:

The shortage affecting Respreeza (human alpha1-proteinase inhibitor) has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

31 March 2021

Shortage of Respreeza (human alpha1-proteinase inhibitor)

powder and solvent for solution for infusion (4,000 mg and 5,000 mg)

Indication	Respreeza is a medicine used in adults with alpha1-proteinase inhibitor deficiency, an inherited disorder that can cause lung problems such as increasing shortness of breath and which may also affect the liver. Respreeza is used to slow down damage to the lungs in patients with severe disease.
Reason for shortage	Beckton Dickinson has recalled an infusion set from the market because sterility could not be guaranteed. This infusion set is co-packed with Respreeza 4,000 mg and 5,000 mg. No adverse events related to potential sterility concerns have been reported. The recalled batches of Respreeza 4,000 mg and 5,000 mg under CSL Behring control (including stock at distribution warehouses) will be returned to CSL Behring manufacturing site in Germany and be repackaged with an infusion set from B. Braun. Until the re-packaged product is available for distribution, supply interruptions are to be expected in Austria, Germany, France and Spain.
Member States affected[1]	• Shortages are expected to occur in Austria, Germany, France and Spain.
Information for healthcare professionals	• Becton Dickinson has recalled an infusion set from the market because sterility could not be guaranteed. This infusion set is co-packed with Respreeza 4,000 mg and 5,000 mg. The recall affected Austria, France, Germany

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

	and Spain. No adverse events related to potential sterility concerns have been reported and the recall was a precaution. • Pharmacists must not dispense any Respreeza 4,000-mg and 5,000-mg packs that contain the Beckton Dickinson infusion sets. A list of affected batches can be found in annex 1 of the DHPC. • Patients who self-administer Respreeza should be contacted and provided with an alternative infusion set (B. Braun). • A direct healthcare professional communication (DHPC) will be sent to healthcare professionals. The DHPC is also available on the EMA website. • As a result of the recall, supply may be limited in Austria, Germany, France and Spain. • In case of supply shortages patients who currently use Respreeza may need to be switched to a licensed alternative treatment if available and deemed necessary by the healthcare professional. • Additional advice may be available from the competent authority in your country.
Information for patients	• Becton Dickinson has recalled an infusion set from the market because sterility could not be guaranteed. This infusion set is co-packed with Respreeza 4,000 mg and 5,000 mg. The recall affected Austria, France, Germany and Spain. No adverse events related to potential sterility concerns have been reported and the recall was a precaution. • Respreeza 4,000 mg or 5,000 mg must not be used with the co-packed Beckton Dickinson infusion set. Contact your pharmacist so that they can supply you with an alternative infusion set (B. Braun). • As a result of the recall, supply may be limited in Austria, Germany, France and Spain. • In case Respreeza becomes unavailable, your doctor will prescribe an alternative treatment if available. If you have any questions you should speak to your doctor or pharmacist. • Additional advice may be available from the competent authority in your country.