EMA/182160/2021 Rev. 3[1,2]

Update of 26 March 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.

24 February 2021

Shortage of Respreeza (human alpha1-proteinase inhibitor)

powder and solvent for solution for infusion (1,000 mg, 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	A limited number of batches of Respreeza will be recalled from the market as a precaution because the company, CSL Behring, could not guarantee that aseptic conditions were met during the manufacturing of the vials. The release of further batches was put on hold while the issue has been addressed.
Member States affected	Shortages are expected to occur in Denmark and France.
Information for healthcare professionals	• A limited number of batches of Respreeza may be recalled from the market in your country as a precaution because the company could not guarantee that aseptic conditions were met during the manufacturing of the vials. • Any recall carried out will be at hospital and pharmacy level. As the recall is precautionary, patients can continue to use vials they already have. A direct healthcare

[1] The list of Member States affected by the shortage has been updated (12 March 2021).
[2] The box announcing the resolution of the shortage has been added (26 March 2021).

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	professional communication (DHPC) with information about the affected batches will be sent to healthcare professionals. The DHPC is also available on the EMA website. • Pharmacies/hospitals are requested to immediately stop the use and the distribution of the affected product batches. Any remaining packages in stock of the affected product batches are to be returned to CSL Behring. • The release of further batches was put on hold while the issue has been addressed. As a result, supply may be limited in Denmark and France. • Patients who currently use Respreeza may need to be switched to a licensed alternative treatment if available and deemed necessary by the healthcare professional. In some circumstances, patients may have to attend clinic for administration of the alternative therapy or home administration by a healthcare professional may be organised, in line with the product information. • Additional advice may be available from the competent authority in your country.
Information for patients	• A limited number of batches of Respreeza may be recalled from hospitals and pharmacies as a precaution because the company could not guarantee that sterile conditions were met during the manufacturing of the vials. The release of further batches was put on hold while the issue has been addressed. As a result, supply may be limited in Denmark and France. • As the recall is precautionary, you can continue to use vials you already have in line with your doctor's advice. • In case Respreeza becomes unavailable, your doctor will prescribe an alternative treatment if available. In some circumstances, you may have to attend clinic for administration of the alternative therapy, or home administration by a healthcare professional may be organised, in line with the product information. • 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.