# Respreeza (alpha1-proteinase inhibitor (human)): risk of missed dose and potential infection due to compromised vial integrity

November 4, 2026

Dear Healthcare Professional,

CSL Behring, in agreement with the European Medicines Agency (EMA) and the <National Competent Authority> would like to inform you of the following:

## *Summary*


- **CSL Behring has received reports of container closure defects affecting specific batches of Respreeza. The affected batches are listed in Table 1 in the Background section.**
- **In the reported cases, when the Mix2Vial transfer device was removed from the product vial after reconstitution, parts of the vial closure became loose or detached which compromised the integrity of the vial. The defects occurred despite the product being prepared and handled in accordance with the instructions for use.**
- **As a result of these defects, it may not be possible to administer the reconstituted product, resulting in missed or delayed doses. If the vial is no longer properly sealed, there is also a risk of microbial contamination which could lead to a serious infection.**
- **If this defect occurs during the reconstitution process as described in the product information, the product should not be administered, and a product complaint should be reported. The defective product vial and transfer device should be retained and submitted to CSL Behring for investigation. Patients will receive replacement products.**
- **Patients receiving Respreeza® in the home setting should be informed by their treating physician or dispensing pharmacy that compromised vial integrity may result in inability to administer the product and that risk of potential infection cannot be excluded if product from an affected vial is administered.**


## *Background on the quality defect*

Respreeza is a human alpha1-proteinase inhibitor which is indicated for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor deficiency (e.g. genotypes PiZZ, PiZ(null), Pi(null,null), PiSZ). Patients are to be under optimal pharmacologic and non-pharmacologic treatment and show evidence of progressive lung disease (e.g. lower forced expiratory volume per second (FEV1) predicted, impaired walking capacity or increased number of exacerbations) as evaluated by a healthcare professional experienced in the treatment of alpha1-proteinase inhibitor deficiency. Product shall be prepared and handled according to the instructions for use which are available in the package leaflet. A delay or omission of a single dose is not expected to result in clinically meaningful consequences for patients.

As of 30 September 2026, CSL Behring has received reports of thirteen (13) confirmed container closure defects, as described, from the affected packed batches listed in Table 1. These batches originated from the same manufacturing filling lot.

CSL Behring is continuing to monitor this issue through ongoing trending and investigational processes to ensure continued product quality and patient safety.

**Table 1** list of Lots affected by the quality defect

| Material | Material Description | Packed Lot | Distributed In: |
|---|---|---|---|
| *1001343* | *FP RESPREEZA 1G M2V DE/ AT* | *P100897449* | *Germany* |
| *1001397* | *FP RESPREEZA 1G M2V FR* | *P100897460* | *France* |
| *1001389* | *FP RESPREEZA 1G M2V CZ/SK/RO* | *P100897645* | *Czech Republic, Romania, Slovakia* |
| *1001385* | *FP RESPREEZA 1G M2V NL* | *P100897648* | *Luxembourg, Netherlands* |
| *1001388* | *FP RESPREEZA 1G M2V UK* | *P100899098* | *United Kingdom* |
| *1001382* | *FP RESPREEZA 1G M2V NORDIC* | *P100899105* | *Sweden, Denmark* |
| *1001387* | *FP RESPREEZA 1G M2V ES/PT* | *P100899813* | *Portugal, Spain* |
| *1001387* | *FP RESPREEZA 1G M2V ES/PT* | *P100904117* | *Portugal* |
| *1001397* | *FP RESPREEZA 1G M2V FR* | *P100906885* | *France* |
| *1001396* | *FP RESPREEZA 1G M2V IE* | *P100907741* | *Ireland* |
| *1001386* | *FP RESPREEZA 1G M2V IT* | *P100907940* | *Italy* |
| *1001383* | *FP RESPREEZA 1G M2V CH* | *P100907953* | *Switzerland* |
| *1001382* | *FP RESPREEZA 1G M2V NORDIC* | *P100936176* | *Sweden, Denmark* |

An assessment of post-marketing safety data from the CSL global safety database was conducted for the affected Respreeza lots and associated packaging batches. No adverse events related to the reported container closure defect were identified.

The benefit-risk profile of all the affected products remains unchanged and favourable.

## *Call for reporting*

Please remain vigilant for signs and symptoms suggestive of infection, including, but not limited to, fever, chills, rigors, malaise or other symptoms of systemic illness. Any suspected adverse reactions should be reported in accordance with the national spontaneous reporting system, including the batch/lot number where available.

## *Company contact point*

< Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>.