



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

## New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 4-7 May 2026 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found on the webpage for [PRAC recommendations on safety signals](#) (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

### 1. Pancreatin – Infection due to viral transmission (EPITT no 20205)

#### Summary of product characteristics

##### 4.4 Special warnings and precautions for use

##### Hepatitis E virus infection

Despite measures taken during manufacturing to reduce the risk, the presence of hepatitis E virus (HEV) in medicinal products containing pancreas powder extracts of animal (porcine) origin is possible.

A cross-sectional study has suggested a higher HEV seroprevalence in patients with cystic fibrosis using pancreatic enzyme replacement therapy than in individuals who do not use pancreatin. This study is subject to important limitations including uncertainty with regards to the timing of past infection, as well as the potential for other sources of HEV. As a precaution, immunosuppressed patients receiving high daily dosing should be advised about symptoms of viral hepatitis and to seek medical attention if such symptoms occur.

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<sup>1</sup> Expected publication date. The actual publication date can be checked on the webpage dedicated to [PRAC recommendations on safety signals](#).



## Package leaflet

### 2. What you need to know before you take [product name]

#### Hepatitis E virus infection

This medicine is of animal (pig) origin. Although steps are taken during manufacturing to reduce the risk, the presence of hepatitis E virus in this medicine is possible. Hepatitis E is a virus that can be present in pigs, which can be spread to humans and may cause infection of the liver.

A study has suggested that people with cystic fibrosis who have taken this medicine may be more likely to have had hepatitis E in the past. However, this study has important limitations. For example, it is unclear when the past infection happened or what the source of the infection was.

As a precaution, if you have a weakened immune system and you are also taking high doses of this medicine, your doctor will tell you about the symptoms of infection with hepatitis E. Talk to your doctor if you develop signs of an infection especially fever, nausea, unusual or changes in stomach pain, or yellowing of the skin or eyes.