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**EPAR summary for the public**

# Enzepi

pancreas powder



This is a summary of the European public assessment report (EPAR) for Enzepi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Enzepi.

For practical information about using Enzepi, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Enzepi and what is it used for?

Enzepi is a medicine used to treat adults and children whose pancreas does not produce enough enzymes (a condition known as pancreatic insufficiency) due to cystic fibrosis or other conditions such as pancreatic cancer. Pancreas enzymes are needed to digest fats, carbohydrates and proteins. A lack of these enzymes leads to poor growth, weight loss, abdominal pain and diarrhoea.

The active substance in Enzepi is pancreas powder which is obtained from pig pancreas. It contains enzymes that help with the digestion of fats, carbohydrates and proteins.

## How is Enzepi used?

Enzepi is available as capsules (5,000; 10,000; 25,000 and 40,000 units). The appropriate dose depends on the symptoms of the disease, amount of fat in the stool, fat content of the diet and the patient's weight. Treatment is started at a low dose, which the doctor may then increase slowly until an appropriate dose is reached.

Enzepi should be taken during meals or snacks with a drink of water or juice. Capsules should be swallowed whole and not chewed or crushed. For patients who cannot swallow capsules, the capsules may be opened and the content mixed with a small amount of acidic food such as fruit puree which should be swallowed immediately without chewing.

Enzepi can only be obtained with a prescription. For further information, see the package leaflet.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

## How does Enzepi work?

The active substance of Enzepi, pancreas powder, is intended to replace missing enzymes in patients whose pancreas does not produce sufficient amounts of them. Enzepi will therefore help the body absorb nutrients better, especially fats.

Pancreas powder is a well-known substance that has been authorised in the treatment of pancreatic insufficiency for many years.

## What benefits of Enzepi have been shown in studies?

Enzepi has been shown to be as effective as an already authorised medicine containing pancreas powder and used in pancreatic insufficiency. In one main study involving 96 patients, treatment with Enzepi led to the absorption of 84% of the fats consumed by patient over 72 hours compared with 85% absorption with the already authorised medicine.

## What are the risks associated with Enzepi?

The most common side effects with Enzepi (which may affect more than 1 in 100 people) are effects on the gut (abdominal pain, bloating, diarrhoea, vomiting, constipation and nausea) and headache. In clinical trials most side effects were mild to moderate in severity. The most important serious side effects observed with all pancreatic enzyme medicines are anaphylactic (allergic) reactions and fibrosing colonopathy (scarring and thickening of the bowel wall).

For the full list of restrictions and all side effects reported with Enzepi, see the package leaflet.

## Why is Enzepi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Enzepi's benefits are greater than its risks and recommended that it be approved for use in the EU.

The CHMP considered that the use of pancreas powder to treat pancreatic insufficiency has been well established in medical practice for more than 20 years. Enzepi was shown to be as effective as the already well-known marketed medicine. In terms of safety, Enzepi's side effects are comparable to other marketed products.

## What measures are being taken to ensure the safe and effective use of Enzepi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Enzepi have been included in the summary of product characteristics and the package leaflet.

## Other information about Enzepi

The European Commission granted a marketing authorisation valid throughout the European Union for Enzepi on 29 June 2016.

The full EPAR for Enzepi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Enzepi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 06-2016.