28 April 2016
EMA/CHMP/291219/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Enzepi

pancreas powder

On 28 April 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Enzepi, intended for the treatment of exocrine pancreatic insufficiency. The applicant for this medicinal product is Aptalis Pharma SAS.

Enzepi will be available as gastro-resistant hard capsules (5,000; 10,000; 25,000 and 40,000 Ph. Eur. units). The active substance of Enzepi is pancreas powder derived from porcine pancreatic glands containing multiple enzymes, including lipases, amylases, and proteases (ATC code: A09AA02). These enzymes catalyse the hydrolysis (in the duodenum and other portions of the proximal small intestine) of fats into monoglycerides, glycerol and free fatty acids, proteins into peptides and amino acids, and starch into dextrins and short chain sugars.

The benefits with Enzepi are its ability to control consequences of exocrine pancreatic insufficiency such as maldigestion and malabsorption of fats, proteins and carbohydrates, which result in nutritional deficiencies. The most common side effects are gastrointestinal complaints [abdominal pain (16%); flatulence (12%); abdominal distension (7%); diarrhoea and vomiting (6%); constipation (5%); nausea (3%)], and headache occurring in approximately 6% of patients. In clinical trials, most of the side effects were mild to moderate in severity. The most important serious adverse reactions observed with pancreatic enzyme medicinal products are anaphylactic reactions and fibrosing colonopathy.

The full indication is:

'Pancreatic enzyme replacement treatment in exocrine pancreatic insufficiency due to cystic fibrosis or other conditions (e.g. chronic pancreatitis, post pancreatectomy or pancreatic cancer).

Enzepi is indicated in infants, children, adolescents and adults.'

It is proposed that Enzepi be subject to medicinal prescription.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.