Pancreatic enzymes

Essential medicine status ✓

EMLc | ATC codes: A09AA02

Indication	Enzyme intestinal ICD11 code: XM5H83
Medicine type	Biological agent
List type	Complementary
Formulations	Oral > Solid: Age-appropriate formulations and doses including lipase, protease and amylase. (EMLc)
EML status history	First added in 2009 (TRS 958)
Sex	All
Age	Children (1 month - 12 years)
Therapeutic equivalence	Medicines within the same pharmacological class can be used
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Pancreatic enzymes
DrugBank	Pancreatic enzymes (Pancrelipase)

Summary of evidence and Expert Committee recommendations

The EMLc Subcommittee reviewed an application for the inclusion of pancreatic enzymes on the EMLc for the management of severe pancreatic insufficiency. the Subcommittee noted that the majority of paediatric patients with pancreatic insufficiency suffer from cystic fibrosis, although several other conditions (e.g. chronic pancreatitis and post-gastric surgery) may also contribute to this condition. It was acknowledged that cystic fibrosis occurs worldwide, and that pancreatic insufficiency may be present in up to 90% of these patients. The resulting malnutrition may lead to a multitude of negative clinical outcomes, including lower life expectancy, poor growth, increased susceptibility to infections and deterioration in lung function. The Subcommittee noted that the application cited several good quality randomised trials, which appeared to support the use of pancreatic enzymes for treatment of pancreatic insufficiency in cystic fibrosis. A significant difference in mean protein and fat absorption was seen when comparing placebo to pancreatic enzyme replacement therapy; however the aim of the majority of studies was to evaluate different doses and formulations. Two randomised controlled studies (1, 2) carried out by the manufacturer of Creon, Solvay, were described, where a co-efficient of fat absorption (CFA) of up to 89.1% following Creon treatment was observed. Similar efficacy was demonstrated between different preparations included in the application. Limited studies involving the use of pancreatic enzyme therapy in the management of conditions other than cystic fibrosis were included in the application, and the Subcommittee noted that the evidence for safety and efficacy in infants younger than six months was limited. It was the conclusion of the Subcommittee that sufficient evidence exists for the efficacy and safety of pancreatic enzyme replacement therapy in children, with resulting improvement in morbidity and mortality of patients with severe pancreatic insufficiency. Given the need for the dose to be monitored and titrated according to clinical response, it was agreed that pancreatic enzymes should be included on the Complementary List. Further discussion by the Subcommittee focussed on the recent warnings about phthalates in the formulations and their potential safety implications. References: 1. A comparison of the efficacy and safety of CREON20 and placebo in the treatment of steatorrhoea in pediatric and adolescent cystic fibrosis patients with clinical exocrine pancreatic insufficiency. Report No. CR 200.0126, Protocol No. S2233101. June 1996 (unpublished document). 2. A comparison of the efficacy and safety of CREON20 and placebo. Report No. CR200.0143, Protocol No. S2233102. May 1997 (unpublished document).