

Cilase - Therapeutic Enzymes

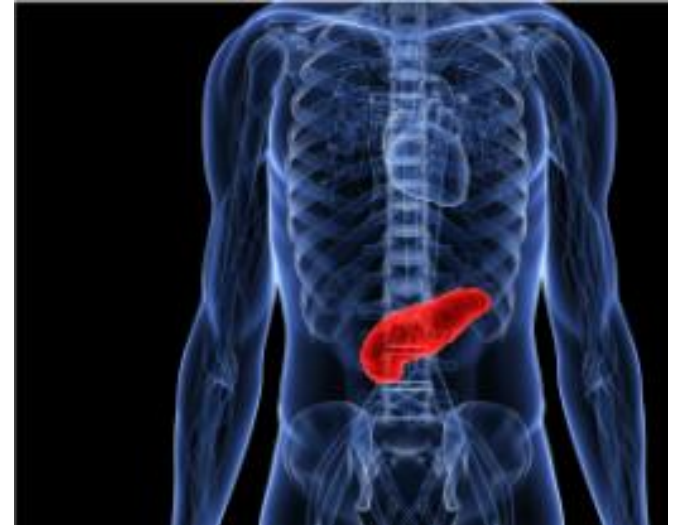
A new active ingredient against pancreatic insufficiency

Exocrine pancreatic insufficiency (EPI)

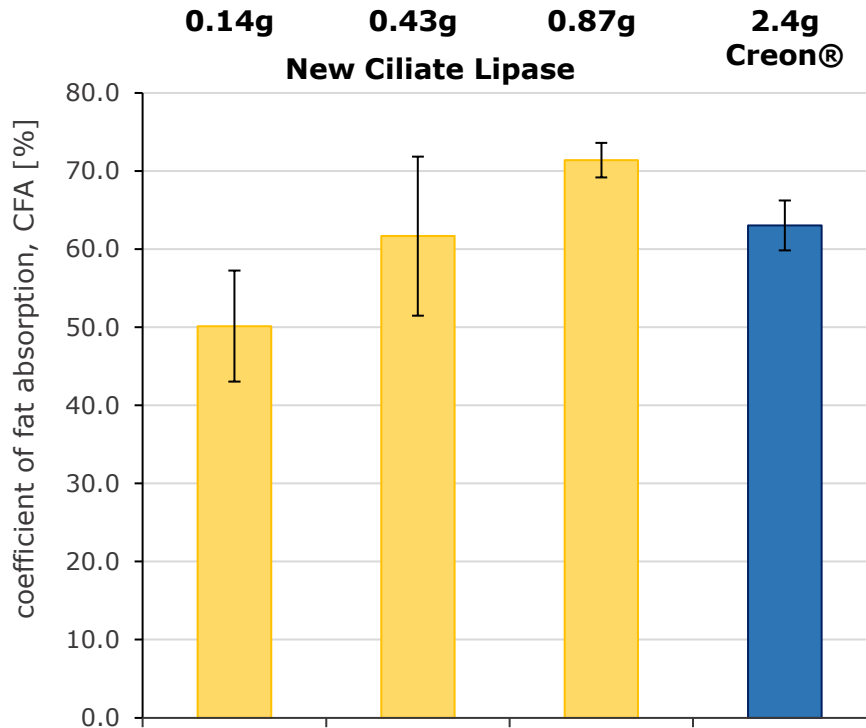
EPI is a serious and life-threatening condition. It is characterized by the deficiency of exocrine pancreatic enzymes, resulting in an inability to digest food properly. This primarily concerns the human lipase, an enzyme that breaks down fat, proteases, enzymes that degrade proteins and amylases, enzymes that split sugar. The deficiency in these enzymes can be responsible for maldigestion, greasy diarrhoea, faecal urge and weight loss.

EPI is caused by severe illness of the human pancreas caused by different reasons, e.g. cystic fibrosis, chronic pancreatitis, pancreatic cancer and many more.

The standard treatment for EPI is oral administration of pancreatic enzymes. All currently approved enzyme preparations are derived from porcine pancreas.



Proven in vivo efficacy in EPI minipigs



- 60g fat were given per meal
- Minipigs were treated with 4000 FIP-U/ g fat
- N=4

- Oral administration of Ciliate Lipase resulted in CFA values comparable to Creon
- Further doubling the amount of Lipase resulted in higher CFA value indicating that maximum effect is not reached with given maximum dose

Cilase - Therapeutic Enzymes



CILASE
equiv. to **90,000**
Lipase FIP Units
150 mg crystallized Lipase
per capsule size 4



Creon®
75,000
Lipase FIP
Units
3 x 300 mg
Pancreatic Powder
capsules size 0

New Ciliate Lipase

Existing porcine enzyme replacement therapy

one pill per meal = significantly reduced daily pill burden

often high number of capsules (~ 4 to 5) per meal necessary

smaller pill size (potentially size 4)

common size 0

great potential to improve patient's adherence and compliance by enhanced convenience

low compliance and poor adherence especially for young sufferers

Cilase - Therapeutic Enzymes



**Lab Scale
(1L, F&E)**



**Pilot Scale Production
(0.9 m³, non-GMP)**



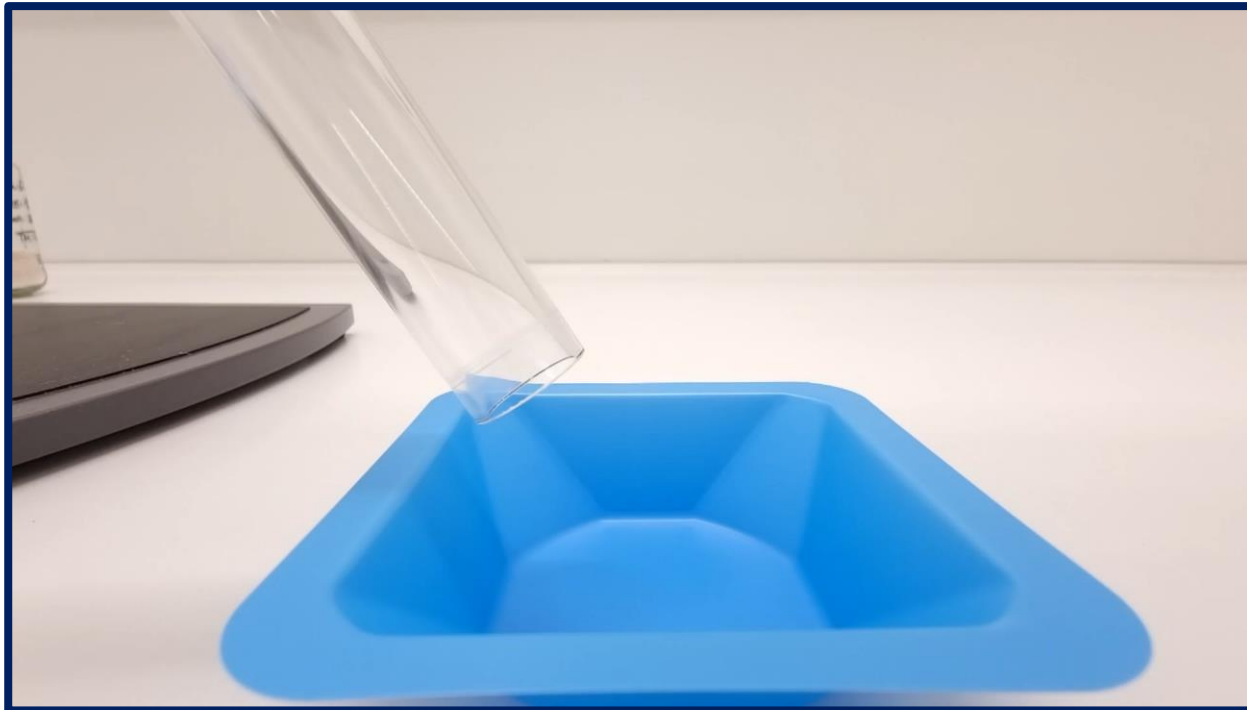
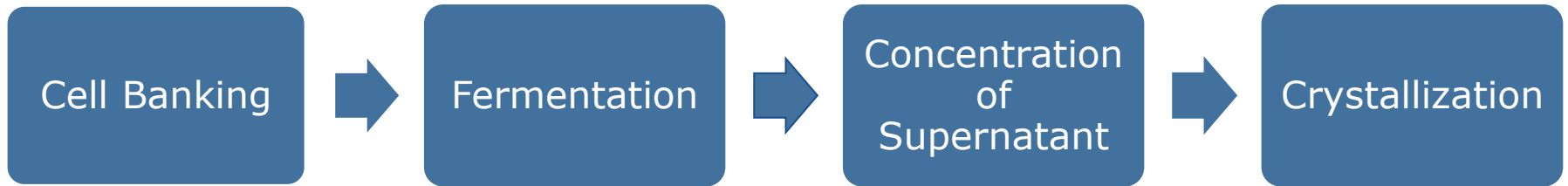
**Industrial Scale Production
(7.5m³, GMP)**

New Ciliate Lipase	Existing porcine enzyme replacement therapy
derived from a reliable and consistent microbial source using recombinant DNA technology	animal derived source
Scalability of production capacities is implemented	limited pig gland resources due to several factors (housing conditions, viral infections)
Use of common/regular microbial bioreactors possible	No reliable supply chain with high constraints especially of high strength capsules
consistent and reliable manufacturing in accordance with relevant GMP regulations and ICH guidelines	High batch to batch variability due to variable potency and inconsistent pharmaceutical properties of pancreatic glands

Cilase - Therapeutic Enzymes



Our production process



Contact



For Questions regarding Cilase contact us directly:

info@cilian.de

