

Micrazym[®] pancrelipase delayed release

High activity pancrelipase / enteric coated micropellets



Overview

Micrazym[®] is a pancreatin enzyme replacement medicine, used to treat digestive system conditions characterized by, or defined as Exocrine Pancreatic Insufficiency (EPI). EPI may be due to pancreas related conditions or other conditions that may have an effect on pancreatic enzyme production, such as cystic fibrosis, chronic pancreatitis, partial or complete pancreatectomy, or other conditions that may exert an indirect effect, such as diabetes.

Micrazym[®]

The medicine consists of enteric coated pancreatine micropellets in capsules. Pancreatin in a blend of naturally derived enzymes (protease, lipase and amylase), which aid in digesting proteins, fats and carbohydrates respectively.

Two Stage Release

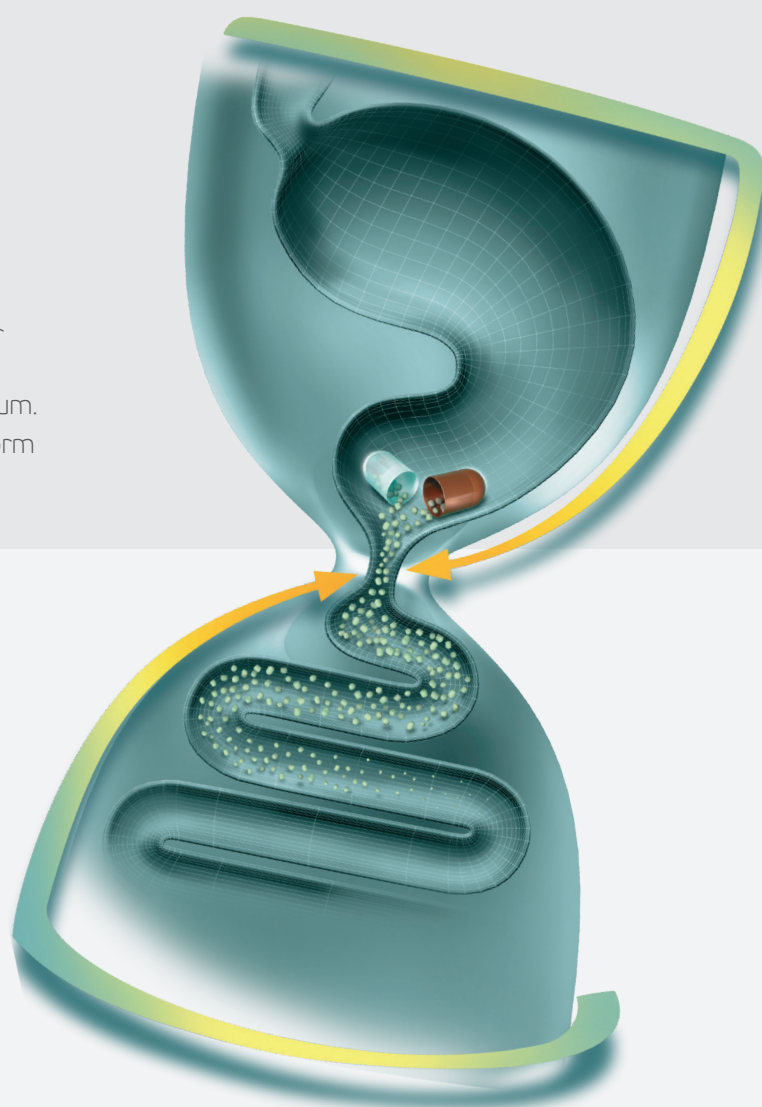
- The enzymes are protected from the gastric acid and their subsequent inactivation.
- Ensure rapid dissolution of the micropellets in the duodenum.
- Enzyme availability where it would naturally occur to perform its intended function.

AVVA Pharmaceuticals Ltd

AVVA Pharmaceuticals Ltd is a European based pharmaceutical company, aiming on becoming a reference innovation hub for the development of biological medicines and new small molecules, with ultimate goal on providing a meaningful and affordable healthcare.

Facility Certifications

- EU GMP
- Saudi Arabia FDA GMP
- EAEU GMP



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AVVA Pharmaceuticals LTD is a research-based pharmaceutical company developing innovative medicines that address common medical needs, based on research into the human microbiome. The Company has an extensive patent portfolio covering pharmaceutical compositions.

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Outstanding Licensing Opportunity:

- ✓ A growing market worldwide with technology entry barrier safeguarding investment. Pancreatic enzyme containing medicines are reimbursable by most healthcare providers and insurance plans worldwide.
- ✓ Global EPI therapeutics market was valued at US\$ 2.27 bln in 2021 and is expected to reach US \$3,75 bln by 2029, registering a CAGR of 6.50% during the forecast period of 2022 to 2029*.
- ✓ High technology entry barrier.
- ✓ A limited number of market competitors worldwide.
- ✓ Retail/OTC and tender business opportunities.



Product General Information:

Product	Form	Strength
Pancreatin (enteric coated micropellets)	Enteric Coated Micropellets in Capsules/Delayed Release	10,000 U, 25,000 U and 40,000 U based in Lipolytic activity

Dossier Information:

Format	Submission Route	Terms of License	Developed as per applicable
euCTD Format	Well Established Use	Dossier License and Product Supply	ICH and EMA guidelines

Product characteristic comparison:

	MICRAZYM [®] 10,000 U	MICRAZYM [®] 25,000 U	MICRAZYM [®] 40,000 U
Lipase	10,000 U	25,000 U	40,000 U
Amylase	7,500 U	19,000 U	25,000 U
Protease	520 U	1,300 U	1,600 U
Pellet size	0.8 - 1.8 mm		

*Bridge Market Research



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