



**Medco Forum Presents:**  
**ZENPEP® (pancrelipase) Delayed-Release Capsules:**  
**Helps Fuel Nutritional Health\* for Patients with**  
**Exocrine Pancreatic Insufficiency**

\*Nutritional health, is defined by improvement in the absorption of essential nutrients from foods such as fats, proteins, carbohydrates, and certain vitamins.

ZENPEP® (pancrelipase) Delayed-Release Capsules is a combination of porcine-derived lipases, proteases, and amylases indicated for the treatment of exocrine pancreatic insufficiency (EPI) due to cystic fibrosis (CF) or other conditions.

Jose M. Nieto, D.O., F.A.C.P., of Borland Groover Clinic's Advanced Therapeutic Endoscopy Center, has prescribed ZENPEP since it first came out in 2009: *"I have a significant number of patients on ZENPEP, and it is generally well-tolerated."*

Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement. Exercise caution when doses of ZENPEP exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day).

In a randomized, double-blind, placebo-controlled, multicenter cross-over study, 34 patients with EPI due to CF (ages 7 to 23 years) were given a high-fat diet and following a 6-9 day dose titration/stabilization period, were randomized to treatment with either ZENPEP or placebo for one week. Following an open-label normalization period, patients were crossed over to the alternative treatment. The primary efficacy endpoint was the change in the mean coefficient of fat absorption (CFA) between ZENPEP and placebo treatment, which was measured from the 72-hour stool sample collected during each inpatient hospitalization period. The use of enzymes other than ZENPEP and drugs affecting gastric pH or motility were not allowed during the trial.

ZENPEP treatment compared to placebo treatment resulted in a significantly higher mean CFA, (88.3% vs. 62.8%, respectively,  $p < 0.001$ ) (primary endpoint) and CNA (87.2% vs. 65.7%, respectively,  $p < 0.001$ ) (secondary endpoint). In addition, 16 out of 32 (50%) patients had a CFA  $> 90\%$  when treated with ZENPEP, and 29 out of 32 (90.6%) patients had a CFA  $> 80\%$  when treated with ZENPEP ( $\geq 85\%$  represents near-normal CFA values in patients with EPI due to CF):

Dr. Nieto notes, *"I would like to highlight the patient programs offered by Aptalis Pharma US, Inc.. As a prescribing physician, one of the biggest factors we have to deal with is how much the treatment will cost the patient and whether their insurance is going to cover it. Aptalis provides patients with assistance programs that can make ZENPEP affordable for many patients."*

Eligible patients who choose to participate in the ZENPEP Patient Support Program receive a patient savings card for prescriptions of ZENPEP, nutritional supplements, refill reminders and patient education materials. Eligible patients can receive:

- Up to \$50 off their ZENPEP prescriptions
- Free vitamins with each ZENPEP refill: Designed for patients who have trouble absorbing the fat-soluble vitamins A, D, E, and K
  - Available in chewable tablets and softgels.
  - Highly absorbable, antioxidant-rich nutritional supplements containing vitamins A, D, E, and K.<sup>†</sup>
  - Levels of vitamins found in program offerings may be too high or inappropriate for some patients.
  - Healthcare professionals should base their selection of vitamin type, formulation, and dosage on an individual patient's specific nutritional needs or deficiencies.
- Educational information about EPI and treatment.

<sup>†</sup>This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.

***Patients can enroll in this program online at [www.ZENPEPsupport.com](http://www.ZENPEPsupport.com) or through Starter Kits available from your Aptalis Sales Representative. Restrictions apply. Please see [www.ZENPEPsupport.com](http://www.ZENPEPsupport.com) for full eligibility requirements.***

### **Important Safety Information**

To avoid irritation of oral mucosa, do not chew ZENPEP or retain in the mouth. Exercise caution when prescribing ZENPEP to patients with gout, renal impairment, or hyperuricemia. There is theoretical risk of viral transmission with all pancreatic enzyme products, including ZENPEP. Rarely, patients taking pancreatic enzyme products with different formulations of the same active ingredient (pancrelipase) have experienced severe allergic reactions, including anaphylaxis, asthma, hives, and pruritus.

Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.

The most common adverse events (≥6% of patients treated with ZENPEP) are abdominal pain, flatulence, headache, cough, decreased weight, early satiety, and constipation.

ZENPEP is not interchangeable with any other pancrelipase product.

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