

Pertzye[®] (pancrelipase) – Expanded Indication and New Formulation

- On October 11, 2016, [Digestive Care and Chiesi USA announced](#) the FDA approval of a new infant-specific formulation and strength of [Pertzye \(pancrelipase\)](#), as a 4,000 lipase units delayed-release capsule, which expands the use of Pertzye to infants up to 12 months of age.
 - Prior to this approval, dosing recommendations were only available for children \geq 12 months of age and adult patients.
 - Pertzye is currently available as an 8,000 lipase units and 16,000 lipase units delayed-release capsule.
- Pertzye is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.
- To support administration to infants, the 4,000 lipase units capsule features a reduced microsphere size compared to the higher strength capsules. The largest microspheres in the 4,000 lipase units capsule are approximately 35 percent smaller than the largest microspheres in the 8,000 and 16,000 lipase units capsules.
- Warnings and precautions of Pertzye include fibrosing colonopathy, potential for irritation to oral mucosa, potential for risk of hyperuricemia, potential viral exposure from the product source, and allergic reactions.
- The most common adverse reactions (\geq 10%) with Pertzye use were diarrhea, dyspepsia, and cough.
- The recommended dose of Pertzye for infants (up to 12 months) is 4,000 lipase units (one capsule) per 120 mL of formula or per breastfeeding.
 - Refer to the drug label for the recommended weight-based dosing of Pertzye for adults and children older than 12 months of age.
 - Dosing should not exceed the recommended maximum dosage set forth by the Cystic Fibrosis Foundation Consensus Conference Guidelines.
 - Pertzye capsules should be swallowed whole and not crushed, chewed or retained in the mouth, to avoid irritation of the oral mucosa.
 - For infants or patients unable to swallow capsules, the contents may be mixed with soft acidic food with a pH of 4.5 or less (eg, applesauce).
- Digestive Care and Chiesi plan to launch the new formulation of Pertzye in November 2016. The delayed-release capsule will contain 4,000 USP units of lipase; 14,375 USP units of protease; and 15,125 USP units of amylase.