

PENTAGASTRIN - pentagastrin solution
AnazaoHealth Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Pentagastrin

DESCRIPTION

Pentagastrin, a diagnostic aid, is supplied as a sterile solution (1.1 ml/5 ml vial) containing:

- 250 micrograms Pentagastrin per ml
- 0.8 mg Methylparaben and 0.2 mg Propylparaben per mL
- 0.9 mg sodium chloride per mL
- pH 8

CLINICAL PHARMACOLOGY

The exact mechanism by which Pentagastrin stimulates gastric acid, pepsin, and intrinsic factor secretion is unknown; however, since Pentagastrin is an analogue of natural gastrin, it is believed that it excites the oxyntic cells of the stomach to secrete to their maximum capacity. Pentagastrin stimulates pancreatic secretion, especially when administered in large intramuscular doses. Pentagastrin also increases gastrointestinal motility by a direct effect on the intestinal smooth muscle. However, it delays gastric emptying time probably by stimulation of terminal antral contractions, which enhance retroperistalsis.

OTHER ACTIONS/EFFECTS Pentagastrin increases blood flow in the gastric mucosa, inhibits absorption of water and electrolytes from the ileum, and promotes sodium and chloride diuresis. It causes contraction of the smooth muscle of the lower esophageal sphincter when administered intravenously. Pentagastrin produces an increase in the motor activity of the colon and rectum

ONSET OF ACTION 10 minutes

TIME TO PEAK EFFECT 20 to 30 minutes

DURATION OF ACTION 60 to 80 minutes

INDICATIONS AND USAGE

1. **Anacidity (diagnosis)**—Pentagastrin is indicated as a diagnostic aid for evaluation of gastric acid secretory function. It is effective in testing for anacidity (achlorhydria) in patients with suspected pernicious anemia, atrophic gastritis, or gastric carcinoma. It is also effective in determining the reduction in acid output after operations for peptic ulcer, such as vagotomy or gastric resection.
2. **Hypersecretory conditions, gastric (diagnosis)**—Pentagastrin is indicated as a diagnostic aid in testing for gastric hypersecretion in patients with suspected duodenal ulcer or postoperative stomal ulcer, and for the diagnosis of Zollinger-Ellison tumor

DOSAGE AND ADMINISTRATION

The intravenous infusion dose has ranged from 0.1 to 12 mcg (0.0001 to 0.012 mg) per kg of body weight per hour administered in a 0.9% sodium chloride injection. It can also be used as a subcutaneous injection for gastric function study with a dose of 6 mcg (0.006 mg) per kg of body weight.

INTERACTIONS

The following may affect pentagastrin's action:

- Antacids, anticholinergics, histamine H2-receptor antagonists, or omeprazole
- Acute, obstructing, penetrating or bleeding peptic ulcers

Storage and Handling

Keep refrigerated between 2° and 8°C. Protect from light

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



PENTAGASTRIN				
pentagastrin solution				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51808-207	
Route of Administration	INTRAVENOUS			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
PENTAGASTRIN (UNII: EF0NX91490) (PENTAGASTRIN - UNII:EF0NX91490)		PENTAGASTRIN	250 ug in 1.6 mL	
Inactive Ingredients				
Ingredient Name		Strength		
METHYLPARABEN (UNII: A218C7H9T)		1.8 mg in 1.6 mL		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		0.2 mg in 1.6 mL		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-207-01	5 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/19/2012	

Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE

Revised: 6/2012

AnazaoHealth Corporation