HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PORCINE SECRETIN FOR INJECTION safely and effectively. See full prescribing information for PORCINE SECRETIN FOR INJECTION.

PORCINE SECRETIN for injection, for intravenous use
Initial U.S. Approval: 2002

----------INDICATIONS AND USAGE----------

Porcine Secretin for Injection is a secretin class hormone indicated for stimulation of:

- pancreatic secretions, including bicarbonate, to aid in the diagnosis of exocrine pancreas dysfunction. (1)
- gastrin secretion to aid in the diagnosis of gastrinoma. (1)
- pancreatic secretions to facilitate the identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP). (1)

----------DOSAGE AND ADMINISTRATION----------

- To avoid an incorrect stimulation test result, discontinue the following drugs for the recommended amount of time prior to administration of Porcine Secretin for Injection:
  - anticholinergic drugs: at least 5 half-lives. (2.1, 5.2, 7.1)
  - H_2-receptor antagonists: at least 2 days. (2.1, 5.3, 7.2)
  - proton pump inhibitors (PPIs): consult the prescribing information for specific PPIs. (2.1, 5.3, 7.2)
- Test Dose: Following reconstitution, administer an intravenous test dose of 0.2 mcg to all patients. (2.1)
- If no acute hypersensitivity reaction is noted for one minute after the test dose, the recommended dosage by indication is shown in the table:

Indication	**Recommended Dosage Regimen (2.2)**
Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of exocrine pancreas dysfunction	0.2 mcg/kg by intravenous injection over 1 minute
Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma	0.4 mcg/kg by intravenous injection over 1 minute
Stimulation of pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during ERCP	0.2 mcg/kg by intravenous injection over 1 minute

- Determine the number of vials to be reconstituted based on the patient's weight and prescribed dose (2.2)
- Porcine Secretin for Injection must be reconstituted with 0.9% Sodium Chloride Injection prior to administration (2.2)
- See full prescribing information for complete information on exocrine test methods (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

For injection: 16 mcg, lyophilized sterile powder in a single-dose vial for reconstitution (3)

----------CONTRAINDICATIONS----------

Patients who:

- develop an acute hypersensitivity reaction in response to the test dose. (4, 5.1)
- have a documented hypersensitivity reaction to porcine products. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity Reactions: Administer a test dose and observe for one minute. If a reaction occurs, administer appropriate treatment. (2.1, 5.1)
- Hyporesponse to Secretin Stimulation Testing in Patients with Vagotomy, Inflammatory Bowel Disease or Receiving Anticholinergics: Discontinue anticholinergic drugs at least 5 half-lives prior to stimulation testing; consider additional testing and clinical assessments for aid in diagnosis. (2.1, 5.2, 7.1)
- Hyperresponse to Secretin Stimulation Testing: Increased gastrin secretion in patients receiving H_2-receptor antagonists or PPIs falsely suggesting gastrinoma; discontinue co-administered drug prior to stimulation testing. Increased pancreatic secretions in patients with alcoholic or other liver disease masking coexisting pancreatic disease; consider additional testing and clinical assessments for aid in diagnosis. (2.1, 5.3, 7.2)

----------ADVERSE REACTIONS----------

Most common adverse reactions (≥2%) are: abdominal discomfort, nausea flushing, burning in stomach, diaphoresis, bradycardia and decreased blood pressure. (6)

To report SUSPECTED ADVERSE REACTIONS, contact ChiRhoClin, Inc. at 1-877-272-4888 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Porcine Secretin for Injection is indicated for the stimulation of:

- pancreatic secretions, including bicarbonate, to aid in the diagnosis of pancreatic exocrine dysfunction.
- gastrin secretion to aid in the diagnosis of gastrinoma, and
- pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

2 DOSAGE AND ADMINISTRATION

2.1 Preparation Prior to Secretin Stimulation Testing, Including Administration of a Test Dose

Discontinue Interacting Drugs

To avoid an incorrect stimulation test result, discontinue the following drugs prior to administration of Porcine Secretin for Injection:

- anticholinergic drugs: at least 5 half-lives prior to testing *[see Warnings and Precautions (5.2), Drug Interactions (7.1)]*
- H_2-receptor antagonists: at least 2 days prior to testing *[see Warnings and Precautions (5.3), Drug Interactions (7.2)]*.
- proton pump inhibitors (PPIs): *C*onsult the prescribing information for specific PPIs *[see Warnings and Precautions (5.3), Drug Interactions (7.2)]*.

Test Dose Preparation and Administration

- Because of a potential hypersensitivity reaction to Porcine Secretin for Injection, administer an intravenous test dose of 0.2 mcg to all patients. A test dose is especially important in patients with a history of atopy *[see Warnings and Precautions (5.1)]*.
- Porcine Secretin for Injection is a lyophilized powder, which requires reconstitution prior to intravenous administration. Prepare the test dose as follows:
    - Dissolve the contents of the Porcine Secretin for Injection 16 mcg vial in 8 mL of 0.9% Sodium Chloride Injection, USP, to yield a concentration of 2 mcg/mL.
    - Shake vigorously to ensure dissolution.
    - Inspect the reconstituted solution visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is seen, discard the reconstituted solution.
    - Withdraw 0.1 mL of the reconstituted solution for administration as the test dose.
    - Use immediately after reconstitution and discard any unused portion.
- Appropriate measures for the treatment of acute hypersensitivity reactions should be immediately available.
- If no hypersensitivity reaction is noted after one minute, administer intravenously the recommended dosage shown in Table 1 for the specific indication *[see Dosage and Administration (2.2)]* slowly over 1 minute.

2.2 Preparation and Dosage Regimen

The recommended dosage regimen of Porcine Secretin for Injection by indication is shown below in Table 1.

TABLE 1: Dosage by Indication

Indication	Recommended Dosage Regimen
Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of exocrine pancreas dysfunction	0.2 mcg/kg by intravenous injection over 1 minute
Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma	0.4 mcg/kg by intravenous injection over 1 minute
Stimulation of pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP)	0.2 mcg/kg by intravenous injection over 1 minute

Preparation of Recommended Dosage

- Porcine Secretin for Injection is a lyophilized powder, which requires reconstitution prior to intravenous administration.
- Determine the number of vials needed for the prescribed dosage based on the patient's weight and recommended dosage. Follow these steps to determine the patient dose:
    - Total dose (mcg) = patient's weight (kg) x prescribed dose (mcg/kg).
    - Total injection volume (mL) = total dose (mcg) divided by the concentration of the reconstituted solution (2 mcg/mL).
    - Round the total injection volume to the nearest tenth of a mL
    - Total number of vials = total injection volume divided by the vial volume (8 mL).
- To reconstitute one vial:
    - Dissolve the contents of the Porcine Secretin for Injection 16 mcg vial in 8 mL of 0.9% Sodium Chloride Injection, USP, to yield a concentration of 2 mcg/mL.
    - Shake vigorously to ensure dissolution.
    - Inspect the reconstituted solution visually for particulate matter and discoloration prior to administration. If particulate matter or discoloration is seen, discard the reconstituted solution.
- Repeat steps above to reconstitute additional vials, as needed, to administer the total dose.
- Use immediately after reconstitution and discard any unused portion.

2.3 Administration and Test Methods

Stimulation testing with Porcine Secretin for Injection should only be performed by physicians with sufficient expertise. Ensure that the institution has established normative ranges for pancreatic exocrine response.

Stimulation of Pancreatic Secretions, including Bicarbonate, to Aid in the Diagnosis of Exocrine Pancreas Dysfunction:

Preparation:

- Instruct patients to fast for at least 12 to 15 hours prior to beginning the test.

Sample Collection: [performed using either the gastroduodenal/Dreiling tube (fluoroscopic) or endoscopic collection method]

- *Gastroduodenal (Dreiling) Tube Collection Method*
    - Pass a radiopaque, double-lumen gastroduodenal tube through the mouth using a guidewire.
    - Under fluoroscopic guidance, place the opening of the proximal lumen in the gastric antrum and the opening of the distal lumen beyond the ampulla of Vater. Confirm the tube positioning and secure the tube.
    - Connect both the proximal (gastric) and distal (duodenal) lumens to low intermittent suction, and apply negative pressure of 25 to 40 mmHg to both lumens.
    - Collect a sample of the duodenal contents and check the pH of the aspirate to verify tube position. Proceed to next step if the duodenal aspirate has a pH of 6 or higher. If the pH is less than 6, reposition the tube.
    - Collect a baseline sample of duodenal fluid for a 15-minute period.
    - Administer an intravenous test dose of 0.2 mcg of Porcine Secretin for Injection and monitor the patient for an acute hypersensitivity reaction for at least 1 minute *[see Dosage and Administration (2.1)]*.
    - If no hypersensitivity reaction occurs, administer Porcine Secretin for Injection at a dose of 0.2 mcg/kg body weight intravenously over 1 minute *[see Dosage and Administration (2.2)]*. For the 60-minute period following the injection, collect four consecutive 15-minute samples of duodenal fluid. Clear the duodenal lumen of the tube with an injection of air after each 15-minute sample collection. Note that wide variation in aspirate volumes is indicative of incomplete aspiration between samples.

- *Endoscopic Collection Method: Endoscopic Pancreatic Function Test (ePFT)*
    - Administer a topical anesthetic spray to the posterior pharynx and place a bite block in the mouth.
    - Perform a standard upper endoscopy by passing the endoscope into the stomach with the patient in the left lateral decubitus position.
    - After gastric insufflation, aspirate all gastric fluid through the endoscope and discard.
    - Pass the endoscope through the pylorus into small intestine and position the tip of the endoscope at the junction of the second and third portion of the duodenum.
    - Aspirate duodenal fluid for several seconds to clear the residual gastric acid from the tube.
    - Collect a baseline aspirate of duodenal fluid (3 to 5 mL) from the post-bulbar duodenum.
    - Administer an intravenous test dose of 0.2 mcg of Porcine Secretin for Injection and monitor the patient for an acute hypersensitivity reaction *[see Dosage and Administration (2.1)]*.
    - If no hypersensitivity reaction occurs, administer Porcine Secretin for Injection at a dose of 0.2 mcg/kg of body weight intravenously over 1 minute *[see Dosage and Administration (2.2)]*.
    - Starting 15 minutes after administration of Porcine Secretin for Injection, collect 4 timed duodenal fluid aspirates (each 3 to 5 mL) at 15-minute intervals. Keep the patient in the left lateral decubitus position throughout the procedure.

Sample Handling and Interpretation:

- Place fluid specimens on ice for immediate measurement of bicarbonate concentration. If samples will not be analyzed immediately, store fluid at –80°C.
- Peak bicarbonate concentrations of 80 to 130 mEq/L after administration indicate normal pancreatic exocrine function.

Stimulation of Gastrin Secretion to Aid in the Diagnosis of Gastrinoma:

Preparation:

- Instruct patients to fast for at least 12 hours prior to beginning the test.

Sample Collection:

- Before administering Porcine Secretin for Injection, draw two blood samples for determination of fasting serum gastrin levels (baseline values).
- Administer an intravenous test dose of 0.2 mcg of Porcine Secretin for Injection and monitor the patient for an acute hypersensitivity reaction *[see Dosage and Administration (2.1)]*.
- After one minute, if there are no hypersensitivity reactions, administer Porcine Secretin for Injection at a dose of 0.4 mcg/kg of body weight intravenously over 1 minute *[see Dosage and Administration (2.2)]*.
- Collect post-injection blood samples after 1, 2, 5, 10, and 30 minutes for determination of serum gastrin concentrations.

Sample Interpretation:

- Gastrinoma is strongly suspected in patients who show an increase in serum gastrin concentration of more than 110 picograms (pg) per mL over baseline levels on any of the post injection samples.

Stimulation of Pancreatic Secretions to Facilitate the Identification of the Ampulla of Vater and Accessory Papilla During Endoscopic Retrograde Cholangiopancreatography (ERCP):

When difficulty is encountered by the endoscopist in identifying the ampulla of Vater or in identifying the accessory papilla in patients with pancreas divisum:

- Administer a test dose of Porcine Secretin for Injection 0.2 mcg intravenously to test for possible acute hypersensitivity reactions *[see Dosage and Administration (2.1)]*.
- After one minute, if there are no hypersensitivity reactions, administer Porcine Secretin for Injection at a dose of 0.2 mcg/kg of body weight intravenously over 1 minute *[see Dosage and Administration (2.2)]*.
- Visible excretion of pancreatic fluid from the orifices of these papillae will enable their identification and facilitate cannulation.

3 DOSAGE FORMS AND STRENGTHS

For injection: 16 mcg of porcine secretin, lyophilized sterile powder in a single-dose vial for reconstitution.

4 CONTRAINDICATIONS

Porcine Secretin for Injection is contraindicated in patients who:

- develop an acute hypersensitivity reaction in response to a test dose*[see Warnings and Precautions (5.1)]*, or
- have a documented hypersensitivity reaction to porcine products.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Because of a potential hypersensitivity reaction to porcine secretin, all patients should receive an intravenous test dose of 0.2 mcg *[see Dosage and Administration (2.1)]*. If no hypersensitivity reaction is observed after one minute, the recommended dose of Porcine Secretin for Injection for the specific indication may be administered intravenously slowly over 1 minute. A test dose is especially important in patients with a history of atopy. Appropriate measures for the treatment of acute hypersensitivity reactions should be immediately available.

5.2 Hyporesponse to Secretin Stimulation Testing

Patients who have undergone vagotomy, have inflammatory bowel disease or are receiving anticholinergic drugs at the time of stimulation testing with Porcine Secretin for Injection, may be hyporesponsive to secretin stimulation. Discontinue anticholinergic drugs at least 5 half-lives prior to stimulation testing *[see Dosage and Administration (2.1)]*. Consider additional testing and clinical assessments for aid in diagnosis.

5.3 Hyperresponse to Secretin Stimulation Testing

Gastrin Secretion

Patients receiving H_2-receptor antagonists or PPIs at the time of stimulation testing with Porcine Secretin for Injection to aid in the diagnosis of gastrinoma may be hyperresponsive to secretin stimulation, falsely suggesting gastrinoma. Discontinue H_2-receptor antagonists at least 2 days prior to stimulation testing. Consult the prescribing information of each specific PPI before administering Porcine Secretin for Injection *[see Dosage and Administration (2.1)]*.

Pancreatic Secretions

Patients with alcoholic or other liver disease may be hyperresponsive to stimulation with Porcine Secretin for Injection, masking the presence of coexisting pancreatic disease. Consider additional testing and clinical assessments for aid in diagnosis.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under varying conditions, adverse reaction rates observed during the clinical trials of a drug cannot always be directly compared to the rates observed during the clinical trials of another drug and may not reflect the adverse reaction rates observed in practice.

The data described below reflect exposure to a single dose of Porcine Secretin for Injection in 957 patients in placebo and active controlled trials. The population consisted of patients ages 1 to 93, 379 males, 574 females, and 4 unspecified; 816 Caucasians, 106 Blacks, 10 Hispanics, 10 American Indians, 8 Asians, 1 Indian, 1 Native Alaskan, and 5 unspecified, with known or suspected diseases of the exocrine pancreas including chronic pancreatitis and pancreatic cancer. Most patients received a single dose of Porcine Secretin for Injection of 0.2 mcg/kg to 0.4 mcg/kg.

The most common adverse reactions reported in at least 2% of patients in clinical trials are shown in Table 2.

TABLE 2
Adverse Reactions in at Least 2% of Patients Treated with a Single-Dose of Porcine Secretin for Injection in Clinical Trials

Adverse Reaction	**Porcine Secretin for Injection Percent Incidence (Number of Patients) N = 957**
Abdominal discomfort	7 (7)
Nausea	7 (7)
Flushing	4 (4)
Burning in stomach	3 (2)
Diaphoresis	3 (2)
Bradycardia	2 (2)
Decreased blood pressure	2 (2)

7 DRUG INTERACTIONS

7.1 Hyporesponse with Anticholinergics

The concomitant use anticholinergic drugs may cause a hyporesponse to stimulation testing with Porcine Secretin for Injection. Discontinue anticholinergic drugs at least 5 half-lives before administering Porcine Secretin for Injection *[see Dosage and Administration (2.1)]*.

7.2 Hyperresponse of Gastrin Secretion with H_2-Receptor Antagonists and PPIs

The concomitant use of H_2-receptor antagonists or PPIs may cause a hyperresponse in gastrin secretion in response to stimulation testing with Porcine Secretin for Injection, falsely suggesting gastrinoma.

Discontinue H_2-receptor antagonists at least 2 days before administering the Porcine Secretin for Injection to aid in the diagnosis of gastrinoma.

The time it takes for serum gastrin concentrations to return to baseline following discontinuation of PPIs is specific to the individual drug. Consult the prescribing information of each specific PPI before administering Porcine Secretin for Injection to aid in the diagnosis of gastrinoma.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on porcine secretin use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with porcine secretin.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

There are no data on the presence of porcine secretin in human milk, the effects of porcine secretin on the breastfed infant, or the effects of porcine secretin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Porcine Secretin for Injection and any potential adverse effects on the breastfed infant from porcine secretin or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of Porcine Secretin for Injection in pediatric patients have not been established.

8.5 Geriatric Use

Among the 957 subjects who have received Porcine Secretin for Injection in clinical trials, 16% were 65 years of age or older and 10% were 75 years of age or older. No overall differences in safety, pharmacological response, or diagnostic effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and the younger patients, but greater sensitivity of some older individuals cannot be ruled out.

11 DESCRIPTION

Porcine Secretin for Injection is a pure sterile, nonpyrogenic, lyophilized white cake powder acetate salt of secretin, a peptide hormone. Secretin has an amino acid sequence identical to the naturally occurring porcine secretin consisting of 27 amino acids. Secretin is chemically defined as follows:

Molecular Weight 3055.5
Empirical Formula: $C_{130}H_{220}N_{44}O_{41}$

Structural Formula:
H-His-Ser-Asp-Gly-Thr-Phe-Thr-Ser-Glu-Leu-Ser-Arg-Leu-Arg-Asp-Ser-Ala-Arg-Leu-Gln-Arg-Leu-Leu-Gln-Gly-Leu-Val-NH_2

The standard unit of biological activity for porcine secretin is the clinical unit (CU).[(1)] One (1) CU of secretin biological activity is equal to 0.2 micrograms (mcg) of porcine secretin.

Porcine Secretin for Injection is available as a 10 mL single-dose vial which contains 16 mcg of purified synthetic porcine secretin, 1 mg of L-cysteine hydrochloride, 20 mg of mannitol, and 9 mg of sodium chloride. When reconstituted in 8 mL of Sodium Chloride Injection USP, each mL of solution contains 2 mcg synthetic porcine secretin for intravenous use. The pH of the reconstituted solution has a range of 3 to 6.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary action of secretin is to stimulate pancreatic ductal cells to secrete pancreas fluid in large volumes that contain bicarbonate.

Secretin is a hormone that is normally released from the duodenum upon exposure of the proximal intestinal lumen to gastric acid, fatty acids and amino acids. Secretin is released from enterochromaffin cells in the intestinal mucosa. Secretin receptors have been identified in the pancreas, stomach, liver, colon, brain and other tissues. When secretin binds to secretin receptors on pancreatic duct cells it opens cystic fibrosis transmembrane conductance regulator (CFTR) channels, leading to secretion of bicarbonate-rich-

pancreatic fluid. Secretin may also work through vagal-vagal neural pathways since stimulation of the efferent vagus nerve stimulates bicarbonate secretion and atropine blocks secretin-stimulated pancreatic secretion.

12.3 Pharmacokinetics

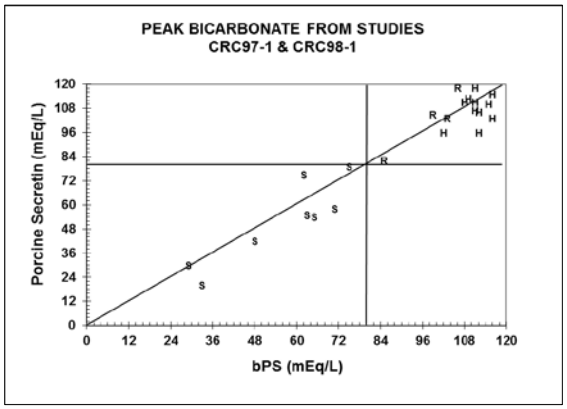
The pharmacokinetic profile of secretin was evaluated in 12 healthy subjects following a single-dose of Porcine Secretin for Injection administered as a 0.4 mcg/kg intravenous bolus. The plasma concentrations of secretin declined to baseline concentrations within 60 to 90 minutes in most of the healthy subjects studied. The elimination half-life was 27 minutes, the clearance was 487 ± 136 mL/minute and the volume of distribution was 2 liters.

14 CLINICAL STUDIES

14.1 Stimulation of Pancreatic Secretions, Including Bicarbonate to Aid in the Diagnosis of Exocrine Pancreas Dysfunction

Porcine Secretin for Injection administered intravenously stimulates the exocrine pancreas to secrete pancreatic juice, which can assist in the diagnosis of exocrine pancreas dysfunction. Normal ranges for pancreatic secretory response to intravenous secretin in patients with defined pancreatic diseases have been shown to vary. One source of variation is related to the inter-investigator differences in operative technique. Two studies examined the relationship of peak bicarbonate concentration observed in three groups of patients: healthy subjects; patients with chronic pancreatitis; patients with a past medical history of chronic pancreatitis and abnormal secretin stimulation test results but with sufficient recovery of exocrine pancreas function to have currently normal test results (Figure 1). Porcine Secretin for Injection was compared to biologically derived porcine secretin (bPS) at a dose of 0.2 mcg/kg for both drugs. All 12 healthy subjects had peak bicarbonate concentrations greater than 80 mEq/L while all patients with chronic pancreatitis had peak bicarbonate concentrations less than 80 mEq/L.

Figure 1



A 45 degree reference line
bPS = biologically derived porcine secretin
S = Sick patients
R = Recovered patients
H = Healthy subjects

The values obtained for Figure 1 were performed by investigators skilled in performing secretin stimulation testing and are to be taken only as guidelines. These results should not be generalized to results of secretin stimulation testing conducted in other laboratories. However, a volume response of less than 2 mL/kg/hour, bicarbonate concentration of less than 80 mEq/L, and bicarbonate output of less than 0.2 mEq/kg/hour are consistent with impaired pancreatic function.

In three crossover studies evaluating 21 different patients with a documented history of chronic pancreatitis, Porcine Secretin for Injection was compared to biologically derived porcine secretin (bPS). All of the patients, treated with either drug, had peak concentrations of less than 80 mEq/L.

14.2 Stimulation of Gastrin Secretion to Aid in the Diagnosis of Gastrinoma

Porcine Secretin for Injection administered intravenously stimulates gastrin release in patients with gastrinoma whereas only small changes in serum gastrin concentrations occur in healthy subjects and patients with peptic ulcer disease. Discriminant analysis was used to establish secretin stimulation testing as an aid in the diagnosis of gastrinoma. An increase from basal levels of greater than or equal to 110 pg/mL was the optimal point separating positive and negative tests. This gastrin response is the basis for the use of secretin as a provocative test in the evaluation of patients in whom gastrinoma is a diagnostic consideration.

In two studies, eight patients with tissue confirmed gastrinoma received 0.4 mcg/kg of Porcine Secretin for Injection and 0.4 mcg/kg of bPS in a crossover design. Serum gastrin concentrations exceeded 110 pg/mL from basal levels in all 8 patients for both drugs tested.

Correlation with clinical data and additional diagnostic modalities should be utilized when considering the diagnosis of gastrinoma.

14.3 Stimulation of Pancreatic Secretion to Facilitate Identification of the Ampulla of Vater and the Accessory Papilla During Endoscopic Retrograde Cholangiopancreatography (ERCP)

In a randomized, placebo controlled crossover study in 31 patients with pancreas divisum undergoing ERCP, Porcine Secretin for Injection at a dose of 0.2 mcg/kg resulted in 25 of 28 successful cannulations of the minor duct compared to 1 of 16 for placebo.

15 REFERENCES

1. Jorpes, E. and Mutt V. On the biological assay of secretin. The reference standard. Acta Physiol Scand. 1966 Mar;66(3):316-25.

16 HOW SUPPLIED/STORAGE AND HANDLING

For injection: 16 mcg of porcine secretin, lyophilized sterile powder in a single-dose vial for reconstitution; NDC # 67066-004-01.

Store at -20°C (freezer). Protect from light.

17 PATIENT COUNSELING INFORMATION

Advise patients of the potential for hypersensitivity reactions *[see Warnings and Precautions (5.1)]*.

Manufactured for:
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004PI01