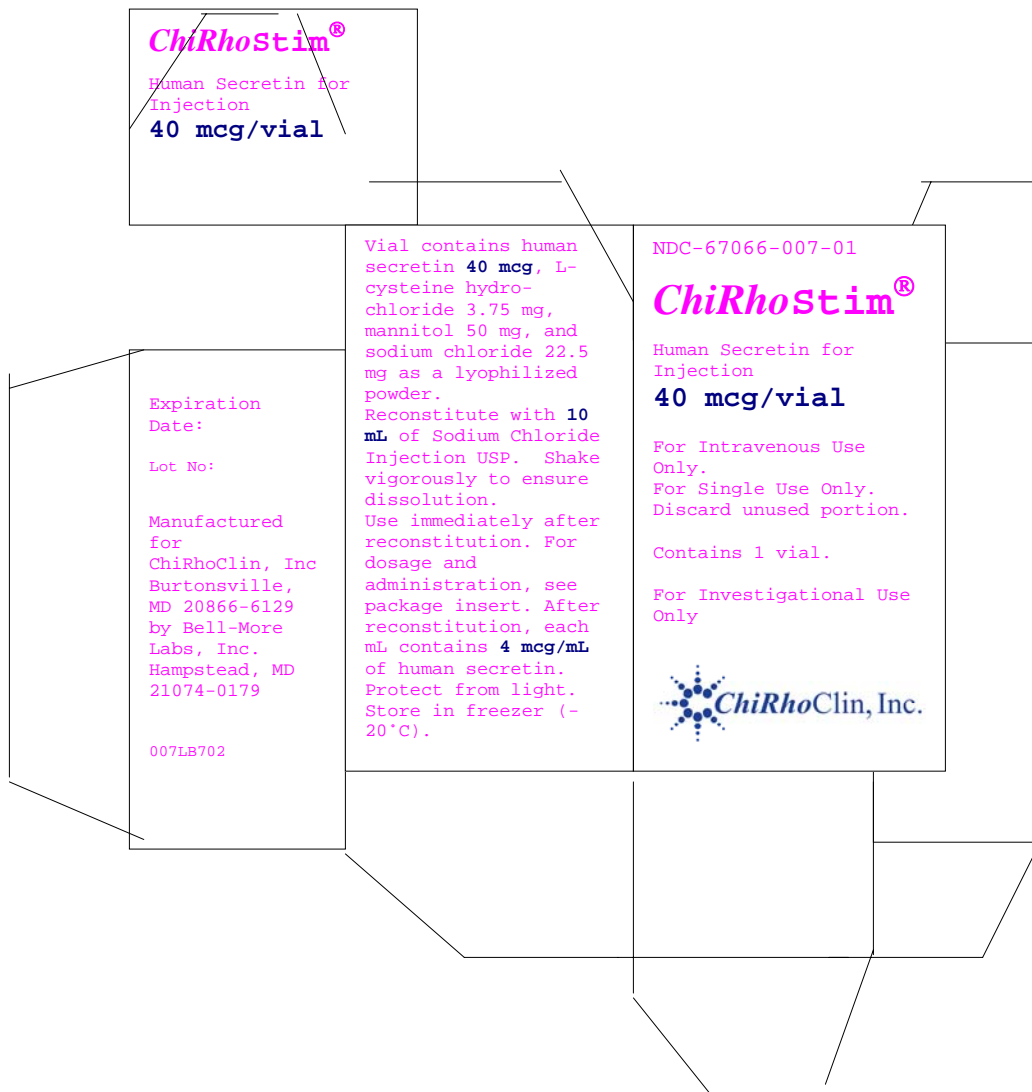


Box Label



Vial Label

NDC-67066-007-01

ChiRhostim[®]

Human Secretin for Injection
40 mcg/vial

For Intravenous Use Only.
For Single Use Only.
Discard unused portion.

For Investigational Use Only



Vial contains human secretin **40 mcg**, L-cysteine hydrochloride 3.75 mg, mannitol 50 mg, and sodium chloride 22.5 mg as a lyophilized powder.

For reconstitution, dosage and administration, see package insert.

Reconstitute with **10 mL** Sodium Chloride Injection USP. Use immediately after reconstitution. After reconstitution, each mL contains **4 mcg/mL** of human secretin. Protect from light.

Store in freezer (-20°C).

Manufactured for ChiRhoClin, Inc.
Burtonsville, MD 20866-6129
By Bell-More Labs, Inc.
Hampstead, MD 21074-0179
007LV704

Expiration date:
Lot No:

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ChiRhoStim® safely and effectively. See full prescribing information for ChiRhoStim®.

ChiRhoStim® (Human Secretin) Injection, lyophilized powder for intravenous use, 16 mcg and 40 mcg vials

Initial U.S. Approval: 2004

RECENT MAJOR CHANGES

Dosage and Administration (2) 6/2007

INDICATIONS AND USAGE

ChiRhoStim® injectables are indicated for:

- Stimulation of pancreatic secretions, including bicarbonate, to aid in the diagnosis of exocrine pancreas dysfunction (1.1)
- Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma (1.2)
- Facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP) (1.3)

DOSAGE AND ADMINISTRATION

Stimulation of pancreatic secretions, including bicarbonate to aid in the diagnosis of exocrine pancreas dysfunction (2.1)

- 0.2 mcg/kg body weight by intravenous injection over 1 minute.

Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma (2.2)

- 0.4 mcg/kg body weight by intravenous injection over 1 minute.

Facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP) (2.3)

- 0.2 mcg/kg body weight by intravenous injection over 1 minute.

DOSAGE FORMS AND STRENGTHS

ChiRhoStim® is available in two strengths:

- As a lyophilized sterile powder in 10 mL vials containing 16 mcg of human secretin. Reconstitute with 8 mL of saline for injection to yield a final concentration of 2 mcg of human secretin /mL (3.1)
- As a lyophilized sterile powder in 10 mL vials containing 40 mcg of human secretin. Reconstitute with 10 mL of saline for injection to yield final concentration of 4 mcg of human secretin /mL (3.2)

CONTRAINDICATIONS

Patients suffering from acute pancreatitis should not receive ChiRhoStim® until the acute episode has subsided (4).

WARNINGS AND PRECAUTIONS

- Allergic Reactions (5.1).
- Vagotomy or Inflammatory Bowel Disease (5.2).
- Alcoholic or Other Liver Disease (5.3).

ADVERSE REACTIONS

Most common adverse reactions (>0.5%) are nausea, flushing, abdominal pain, and vomiting (6).

To report SUSPECTED ADVERSE REACTIONS, contact ChiRhoClin, Inc. at 301-476-8388 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

The concomitant use of anticholinergic agents may make patients hyporesponsive, i.e., may produce a false result (7). Results of secretin testing in these patients should be interpreted with caution.

USE IN SPECIFIC POPULATIONS

The safety evaluation of ChiRhoStim® in geriatric patients showed no difference from the safety evaluation in the general population (8.5).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 6/2007

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE

- 1.1 Stimulation of pancreatic secretions, including bicarbonate to aid in the diagnosis of Exocrine Pancreas Dysfunction
- 1.2 Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma
- 1.3 Facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP)

2 DOSAGE AND ADMINISTRATION

- 2.1 Stimulation of pancreatic secretions, including bicarbonate to aid in the diagnosis of Exocrine Pancreas Dysfunction
- 2.2 Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma
- 2.3 Facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP)
- 2.4 Administration

3 DOSAGE FORMS AND STRENGTHS

- 3.1 ChiRhoStim® single dose 16 mcg/10 ml vial
- 3.2 ChiRhoStim® single dose 40 mcg/10 mL vial

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

- 5.1 Allergic Reactions
- 5.2 Vagotomy or Inflammatory Bowel Disease
- 5.3 Alcoholic or Other Liver Disease

6 ADVERSE REACTIONS

7 DRUG INTERACTIONS

8 USE IN SPECIFIC POPULATIONS

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- 16.1 Supplied
- 16.2 Storage

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ChiRhoStim® is indicated for:

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

2 DOSAGE AND ADMINISTRATION

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

0.2 mcg/kg body weight by intravenous injection over 1 minute.

Gastroduodenal (Dreiling) Tube Collection Method⁽¹⁾:

A radiopaque, double-lumen tube is passed through the mouth following a 12-15 hour fast. Under fluoroscopic control, the opening of the proximal lumen of the tube is placed in the gastric antrum and the opening of the distal lumen just beyond the papilla of Vater. The positioning of the tube must be confirmed and the tube secured prior to synthetic human secretin testing. Intermittent negative pressure of 25-40 mmHg is applied to both lumens and maintained throughout the test. When duodenal contents have a pH of ≥ 6 , a baseline sample of duodenal fluids is collected for a 10 minute period. A test dose of ChiRhoStim® 0.2 mcg if using the 16 mcg vial (0.1 mL) or 0.4 mcg if using the 40 mcg vial (0.1 mL) is injected intravenously to test for possible allergies. After one minute, if there are no signs of allergic reaction, ChiRhoStim® at a dose of 0.2 mcg/kg of body weight is injected intravenously over 1 minute. Duodenal fluid is collected for 60 minutes thereafter. The aspirate is divided into four collection periods of fifteen minutes each. The duodenal lumen of the tube is cleared with an injection of air after collection of each sample. Wide variation in volume of the aspirate is indicative of incomplete aspiration. Each sample of duodenal fluid is to be chilled and subsequently analyzed for volume and bicarbonate concentration. Exocrine pancreas dysfunction typically associated with chronic pancreatitis is indicated if the peak bicarbonate concentration for any sample ≤ 80 mEq/L.

Endoscopic Collection Method: Endoscopic Pancreatic Function Test (ePFT)⁽²⁻⁴⁾:

After assessment of patients for sedation and analgesia, a test dose of ChiRhoStim® 0.2 mcg if using the 16 mcg vial (0.1 mL) or 0.4 mcg if using the 40 mcg vial (0.1 mL) is injected intravenously to test for possible allergies. After one minute, if there are no signs of allergic reaction, ChiRhoStim® at a dose of 0.2 mcg/kg of body weight is injected intravenously over 1 minute. An upper endoscopy is performed with conscious sedation, after topical anesthetic. All gastric fluid is aspirated through the endoscope and discarded. After small bowel intubation to the

junction of the second and third portion of the duodenum, fluid is aspirated for 1 to 3 minutes and collected in 5 separate specimen traps at baseline (0), 15, 30, 45, and 60 minutes after secretin injection. The patients remain intubated with the upper endoscope for one hour in the left lateral decubitus position. Boluses of meperidine and midazolam in a 25:1 mg ratio are administered to maintain analgesia and sedation during the 1-hour procedure. Each sample of duodenal fluid is to be chilled and subsequently analyzed for volume and bicarbonate concentration. Exocrine pancreas dysfunction typically associated with chronic pancreatitis is indicated if the peak bicarbonate concentration for any sample \leq 80 mEq/L.

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

0.4 mcg/kg body weight by intravenous injection over 1 minute.

The patient should fast for at least 12 hours prior to beginning the test. Prior to injection of ChiRhoStim[®], two blood samples are drawn for determination of fasting serum gastrin levels (baseline values). Subsequently, a test dose of ChiRhoStim[®] 0.2 mcg if using the 16 mcg vial (0.1 mL) or 0.4 mcg if using the 40 mcg vial (0.1 mL) is injected intravenously to test for possible allergies. If there are no signs of allergic reaction, ChiRhoStim[®] at a dose of 0.4 mcg/kg of body weight is injected intravenously over 1 minute; post-injection blood samples are collected after 1, 2, 5, 10, and 30 minutes for determination of serum gastrin concentrations.

Gastrinoma is strongly indicated in patients who show an increase in serum gastrin concentrations of 110 pg/mL over basal level on any of the post injection samples.

2.3 Facilitation of the Identification of the Ampulla of Vater and Accessory Papilla During Endoscopic Retrograde Cholangiopancreatography (ERCP) to aid in cannulation of the pancreatic duct:

0.2 mcg/kg body weight by intravenous injection over 1 minute.

Administration of ChiRhoStim[®] may be given when difficulty is encountered by the endoscopist in identifying the ampulla of Vater for various reasons including: anatomic deformity secondary to prior surgery, radiation therapy, peptic ulcer disease, tumors, etc. or in identifying the accessory papilla in patients with pancreas divisum. A test dose of ChiRhoStim[®] 0.2 mcg if using the 16 mcg vial (0.1 mL) or 0.4 mcg if using the 40 mcg vial (0.1 mL) is injected intravenously to test for possible allergies. If there are no signs of allergic reaction, a dose of 0.2 mcg/kg of body weight intravenously over 1 minute may be administered and will result in visible excretion of pancreatic fluid from the orifices of these papillae enabling their identification and facilitating their cannulation.

2.4 ADMINISTRATION

ChiRhoStim[®] 16 mcg vial:

Dissolve the contents of the ChiRhoStim[®] 16 mcg vial in 8 mL of Sodium Chloride Injection USP, to yield a concentration of 2

mcg/mL. Shake vigorously to ensure dissolution. Use immediately after reconstitution and discard any unused portion.

ChiRhoStim® 40 mcg vial:

Dissolve the contents of the ChiRhoStim® 40 mcg vial in 10 mL of Sodium Chloride Injection USP, to yield a concentration of 4 mcg/mL. Shake vigorously to ensure dissolution. Use immediately after reconstitution and discard any unused portion.

For both strengths, the reconstituted drug product should be inspected visually prior to administration. If particulate matter or discoloration is seen, the product should be discarded.

3 DOSAGE FORMS AND STRENGTHS

ChiRhoStim® is available in two strengths:

As a lyophilized sterile powder in 10 mL vials containing 16 mcg of human secretin.

As a lyophilized sterile powder in 10 mL vials containing 40 mcg of human secretin.

4 CONTRAINDICATIONS

Patients suffering from acute pancreatitis should not receive ChiRhoStim® until the acute episode has subsided.

5 WARNINGS AND PRECAUTIONS

5.1 Allergic Reactions

Because of a potential allergic reaction to ChiRhoStim® patients should receive an intravenous test dose of 0.1 mL of the respective reconstituted vial. If no signs of allergic reaction are noted after one minute, the recommended dose may be injected slowly over 1 minute. A test dose is especially important in patients with a history of atopic allergy and/or asthma. Appropriate measures for the treatment of acute hypersensitivity reactions should be immediately available. No allergic reactions were observed after the test dose or full dose of synthetic human secretin in 584 patients and volunteers.

5.2 Vagotomy or Inflammatory Bowel Disease

Patients who have undergone vagotomy or who have inflammatory bowel disease may be hyporesponsive to secretin stimulation. This response does not indicate pancreatic disease, and results of secretin stimulation tests in these patients should be interpreted with caution.

5.3 Alcoholic or Liver Disease

A greater than normal volume response to secretin stimulation, which may mask coexisting pancreatic disease, is occasionally encountered in patients with alcoholic or other liver disease. Results of secretin stimulation tests in these patients should thus be interpreted with caution.

6 ADVERSE REACTIONS

Mild to moderate adverse reactions have been noted for synthetic human secretin in clinical studies in 533 patients and 51 healthy volunteers. Two severe adverse reactions, nausea and abdominal pain, occurred in one patient. Table 1 details the type and number of patients with adverse reactions.

TABLE 1
ADVERSE REACTIONS WITH CHIRHOSTIM[®]

Adverse Reaction	N = 584 Incidence (Patients)
Nausea	11 (11)
Flushing	4 (4)
Early removal of Dreiling tube	3 (3)
Abdominal pain	3 (3)
Vomiting	3 (3)
Increased heart rate	2 (2)
Mild Pancreatitis	2 (2)
Upset stomach	2 (2)
Anxiety	1 (1)
Burning in stomach or abdomen	1 (1)
Clammy skin	1 (1)
Decreased O ₂ saturation	1 (1)
Diarrhea	1 (1)
Faintness	1 (1)
Hypotension	1 (1)
Infiltrated IV	1 (1)
Oral secretions increased	1 (1)
Sedation	1 (1)
Slow heart rate (57 bpm)	1 (1)
Tingling in legs	1 (1)
Unresponsive	1 (1)
Warm sensation in abdomen	1 (1)
Warm sensation in face	1 (1)

Of the 584 patients and healthy volunteers treated with ChiRhoStim[®], a total of 29 patients (5%) had at least one adverse reaction.

7 DRUG INTERACTIONS

The concomitant use of anticholinergic agents may make patients hyporesponsive to secretin stimulation and may produce a false result. Any results of secretin stimulation tests in these patients should thus be interpreted with caution.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies have not been conducted with synthetic human secretin. It is also not known whether synthetic human secretin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Synthetic human secretin should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

It is not known whether synthetic human secretin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when synthetic human secretin is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Among the 533 patients who have received ChiRhoStim[®] in clinical trials 18% were 65 years of age or older and 6% were 75 years of age or older. Dosing was the same as that for the overall population of patients. No overall differences in safety, pharmacologic response, or diagnostic effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and the younger patients, but greater sensitivity of some older individuals to ChiRhoStim[®] cannot be ruled out.

11 DESCRIPTION

Human secretin is a gastrointestinal peptide hormone produced by cells in the duodenum in response to acidification. ChiRhoStim[®] (human secretin as the acetate) is a purified synthetic peptide with an amino acid sequence identical to the naturally occurring hormone. Synthetic human secretin is chemically defined as follows:

Molecular Weight 3039.44

Empirical Formula: C₁₃₀H₂₂₀N₄₄O₃₉

CAS # 108153-74-8

Structural Formula:

His-Ser-Asp-Gly-Thr-Phe-Thr-Ser-Glu-Leu-Ser-Arg-Leu-Arg-Glu-Gly-Ala-Arg-Leu-Gln-Arg-Leu-Leu-Gln-Gly-Leu-Val-NH₂

ChiRhoStim[®] is available in two strengths:

- As a 10 ml vial which contains 16 mcg of purified synthetic human secretin, 1.5 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 human secretin for intravenous use. The pH of the reconstituted solution has a range of 3 to 6.5.

- As a 10 ml vial which contains 40 mcg of purified synthetic human secretin, 3.75 mg of L-cysteine hydrochloride, 50 mg of mannitol, and 22.5 mg of sodium chloride per vial. When reconstituted in 10 mL of Sodium Chloride Injection USP, each mL of solution contains 4 mcg synthetic human secretin for intravenous use. The pH of the reconstituted solution has a range of 3 to 6.5.

12 CLINICAL PHARMACOLOGY

The primary action of ChiRhoStim® is to increase the volume and bicarbonate content of secreted pancreatic juices. The standard unit of activity used for ChiRhoStim® is the clinical unit as defined in the literature.⁽⁵⁾ Synthetic human secretin (sHS), synthetic porcine secretin (sPS) and biologically derived porcine secretin (bPS) have been evaluated and compared in the validated cat bioassay used for release of bPS. sHS and sPS were found to have similar pharmacological activity in terms of stimulating the exocrine pancreas to secrete juice and bicarbonate. The potency correlation with bPS for both sHS and sPS was 0.2 mcg (sHS or sPS) corresponding to 1 CU (bPS). The biological activity of sHS and sPS was approximately 5.0 CU per mcg as opposed to 3.0 CU per mcg for bPS.

12.1 Mechanism of Action

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 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. See references 6 and 7 for additional details on mechanism of action of secretin and feedback controls.

12.3 Pharmacokinetics

The PK profile for synthetic human secretin was evaluated in 12 normal subjects. After intravenous bolus administration of 0.4 mcg/kg, synthetic human secretin concentration rapidly declines to baseline secretin levels within 90 to 120 minutes. The elimination half-life of synthetic human secretin is 45 minutes. The clearance of synthetic human secretin is 580.9 ± 51.3 mL/min and the volume of distribution is 2.7 L.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of synthetic human secretin. Studies to evaluate the potential for impairment of fertility or mutagenicity of synthetic human secretin have not been performed.

13.2 Animal Toxicology and/or Pharmacology

A single intravenous dose of synthetic human secretin at 20 mcg/kg was not lethal to mice or rabbits.

14 CLINICAL STUDIES

14.1 Stimulation of pancreatic secretions, including bicarbonate to aid in the diagnosis of Exocrine Pancreas Dysfunction:

ChiRhoStim[®] 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 disease have been shown to vary. One source of variation is related to the inter-investigator differences in operative technique.

In two crossover studies (CRC98-2 and CRC99-9), a total of 18 patients with a documented history of chronic pancreatitis were given sHS, sPS and bPS. The results appear in Figures 1 and 2. In another study, 35 normal volunteers were given sHS. The results appear in Figures 1 and 2.

FIGURE 1

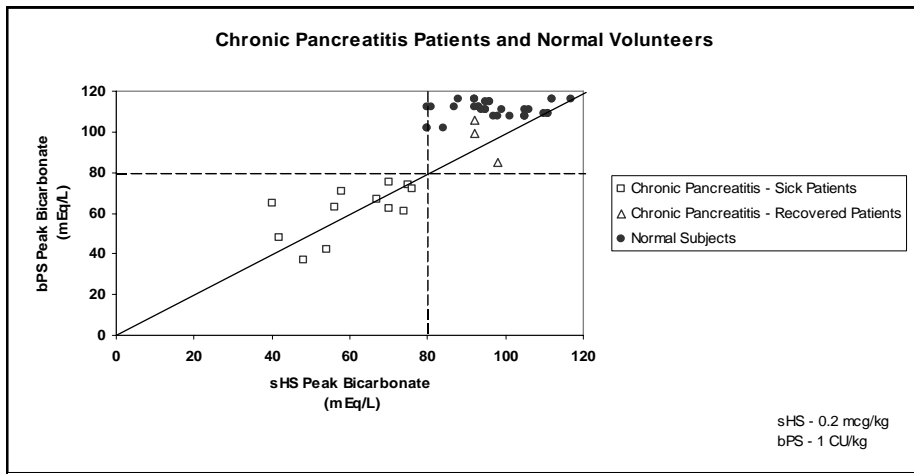
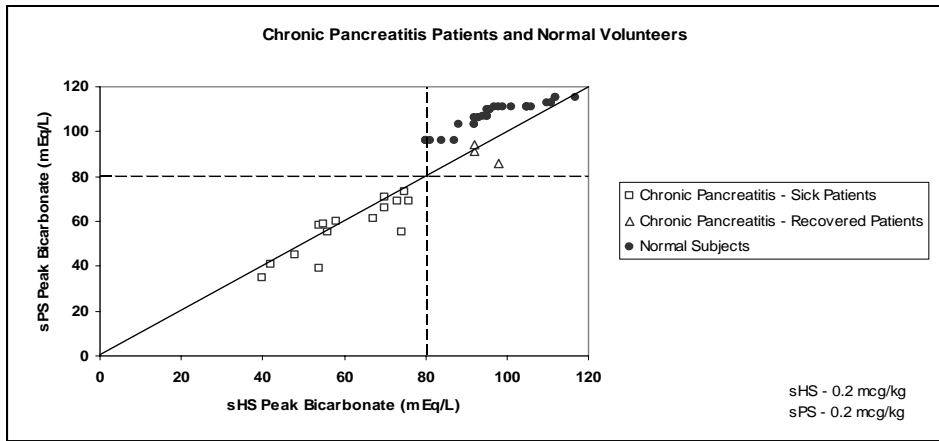


FIGURE 2



The values obtained for Figures 1 and 2 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/hr, bicarbonate concentration of less than 80 mEq/L, and a bicarbonate output of less than 0.2 mEq/kg/hr are consistent with impaired pancreatic function.

A physician or institution planning to perform secretin stimulation testing as an aid to the diagnosis of pancreatic disease should begin by assessing enough normal subjects (>5) to develop proficiency in proper techniques and to generate normal response ranges for the commonly assessed parameters for pancreatic exocrine response to ChiRhoStim®.

In three crossover studies (CRC 98-1, CRC 98-2, and CRC 99-9) evaluating 21 different patients with a documented history of chronic pancreatitis, synthetic human secretin (sHS) was compared to synthetic porcine secretin (sPS) and biologically derived secretin (bPS). All of the patients treated with these drugs had peak bicarbonate concentrations of < 80 mEq/L.

Pancreatic secretory response to intravenous synthetic human secretin in 35 normal healthy subjects demonstrated a mean peak bicarbonate concentration of 100 mEq/L and a mean total volume over one hour of 260.7 mL. All 35 subjects had peak bicarbonate concentrations \geq 80 mEq/L.

14.2 Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma

ChiRhoStim® administered intravenously stimulates gastrin release in patients with gastrinoma (Zollinger-Ellison Syndrome), whereas no or only small changes in serum gastrin concentrations occur in normal subjects and in patients with duodenal ulcer disease. Deveney, et al. established the high sensitivity and specificity of the secretin stimulation test to aid in the diagnosis of gastrinoma and found using discriminant analysis that an increase from baseline of \geq 110 pg/mL was the optimal point separating positive and negative tests.⁽⁸⁾ This gastrin response is the basis for the use of synthetic human secretin as a provocative test in the evaluation of patients in whom gastrinoma is a diagnostic consideration.

In a three way crossover study of 6 patients with tissue diagnosed gastrinoma, there was agreement among synthetic human secretin (ChiRhoStim®), synthetic porcine secretin and biologically derived porcine secretin regarding gastrin levels. Serum gastrin levels were reported to be >110 pg/mL for all secretin products tested after stimulation with 0.4 mcg/kg secretin. Testing of ChiRhoStim® in 12 healthy volunteers demonstrated completely negative results for gastrinoma.

14.3 Facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP) to assist in cannulation of the pancreatic ducts

In a randomized, placebo controlled crossover study in 24 patients with pancreas divisum undergoing ERCP, synthetic human secretin administration at a dose of 0.2 mcg/kg resulted in 16 of 24 successful cannulations of the minor duct compared to 2 of 24 for placebo.

15 REFERENCES

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6. Chey WY, Chang T-M, Secretin. In: Kasin AJ. Editor. Handbook of Biologically Active Peptides. Elsevier, Amsterdam. 2006;1115-1122.
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16 HOW SUPPLIED/STORAGE AND HANDLING

ChiRhoStim[®] 16 mcg vial NDC # 67066-005-01
ChiRhoStim[®] 40 mcg vial NDC # 67066-007-01

16.1 Supplied

ChiRhoStim[®] is supplied in two strengths:

As a lyophilized sterile powder in vials containing 16 mcg of human secretin.

As a lyophilized sterile powder in vials containing 40 mcg of human secretin.

16.2 Storage

The unreconstituted product should be stored at -20°C (freezer). Expiration date is marked on the label. Protect from light.

17 PATIENT COUNSELING INFORMATION

Since there is no data on pregnant or nursing mothers, physicians should discuss these matters with the patient before using this product.

ChiRhoStim[®] is a registered trademark of ChiRhoClin, Inc.

Manufactured for:
ChiRhoClin, Inc
Burtonsville, MD 20866-6129

Manufactured by:
Bell-More Labs, Inc.
Hampstead, Maryland 21074-0179

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