SINCALIDE - sincalide injection, powder, lyophilized, for 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.

Sincalide

Dear Medical Professional,

Per your order, we have compounded Sincalide as a sterile lyophilized powder, sealed under nitrogen. The characteristics of this compounded preparation are as follows

DESCRIPTION

- Upon reconstitution with 3 ml normal saline, the vial contains
  - 1 mcg/ml Sincalide
  - 5 mg Mannitol
- Lyophilized product should be stored at room temperature. After reconstitution with normal saline, the vial can be stored in the refrigerator for use within 12 hours.

Normal dosing is 0.02 micrograms per kilogram patient weight. A 70 kg patient would receive 1.4 mcg or 1.4 ml

CLINICAL PHARMACOLOGY

Sincalide, a synthetically prepared C-terminal octapeptide of the natural hormone cholecystokinin, induces contraction of the gallbladder muscle, resulting in reduction of gallbladder size and evacuation of bile. Also, Sincalide, like cholecystokinin, stimulates secretion of pancreatic enzymes;Sincalide decreases intestinal transit time; delays gastric emptying; decreases esophageal sphincter tone; inhibits gastric secretions; and stimulates intestinal muscle. Maximum contraction (40% reduction in size) of gallbladder occurs 5 to 15 minutes after injection. Gallbladder returns to basal size within 1 hour

INDICATIONS AND USAGE

Sincalide may be used: to stimulate gallbladder contraction, as may be assessed by various methods of diagnostic imaging, or to obtain by duodenal aspiration a sample of concentrated bile for analysis of cholesterol, bile salts, phospholipids, and crystals; to stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology; to accelerate the transit of a barium meal through the small bowel, thereby decreasing the time and extent of radiation associated with fluoroscopy and x-ray examination of the intestinal tract

CONTRAINDICATIONS

Gallbladder stones (stimulation of gallbladder contraction in patients with small gallbladder stones may lead to the evacuation of the stones from the gallbladder resulting in their lodging in the cystic duct or in the common bile duct; however, this is unlikely with usual doses of Sincalide since complete contraction of the gallbladder is not induced.)

ADVERSE REACTIONS

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate) – not necessarily inclusive:

- Those indicating need for medical attention with an Incidence that is less frequent or rare include allergic reaction (shortness of breath, skin rash) , hypotension (dizziness, lightheadedness, or fainting) or Increase in blood pressure
- More frequent adverse reaction include Gastrointestinal effects (nausea, abdominal or stomach pain, cramps, or discomfort) – 20% incidence, diarrhea, dizziness , flushing or redness of skin , headache , increased sweating , numbness , sneezing , urge to have bowel movement or vomiting

Note: The less frequent side effects listed occur in less than 1% of patients, except for diarrhea, which occurs in about 2% of patients. The above side effects are generally mild and of short duration; they are usually lessened by a slower injection rate

DOSAGE AND ADMINISTRATION

To reconstitute, aseptically add 3 mL of preservative free 0.9% sodium chloride to the vial and swirl. This solution may be kept at room temperature and should be used within 8 hours of reconstitution, after which time any unused portion should be discarded.

The vial should be inspected visually for particulate matter and discoloration prior to administration.

For prompt contraction of the gallbladder, a dose of 0.02 mcg sincalide per kg (1.4 mcg/70 kg) is injected intravenously over a 30- to 60-second interval; if satisfactory contraction of the gallbladder does not occur in 15 minutes, a second dose, 0.04 mcg sincalide per kg, may be administered. To reduce the intestinal side effects, an intravenous infusion may be prepared at a dose of 0.12 mcg/kg in 100 mL of Sodium Chloride Injection USP and given at a rate of 2 mL per minute; alternatively, an intramuscular dose of 0.1 mcg/kg may be given.

To accelerate the transit time of a barium meal through the small bowel, administer Sincalide after the barium meal is beyond the proximal jejunum. (Sincalide, like cholecystokinin, may cause pyloric contraction.) The recommended dose is 0.04 mcg sincalide per kg (2.8 mcg/70 kg) injected intravenously over a 30- to 60- second interval; if satisfactory transit of the barium meal has not occurred in 30 minutes, a second dose of 0.04 mcg sincalide per kg may be administered. For reduction of side effects, a 30-minute IV infusion of sincalide [0.12 mcg per kg (8.4 mcg/70 kg) diluted to approximately 100 mL with Sodium Chloride Injection USP] may be administered

Storage and Handling

The preparation should be stored at room temperature

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

SINCALIDE

sincalide injection, powder, lyophilized, for solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-203
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SINCALIDE (UNII: M03GIQ7Z6P) (SINCALIDE - UNII:M03GIQ7Z6P)	SINCALIDE	3 ug

Inactive Ingredients	
Ingredient Name	**Strength**
MANNITOL (UNII: 3OWL53L36A)	5 mg

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-203-01	1 in 1 PACKAGE		

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