



Concurrent administration of sincalide with secretin increases both the volume of pancreatic secretion and the out-put of bicarbonate and enzymes. This combined effect of secretin and sincalide permits the assessment of specific pancreatic function through measurement and analysis of the duodenal aspirate.

**12.2 Pharmacodynamics**

Following an intravenous (bolus) injection of 0.02 mcg/kg of sincalide, maximal contraction of the gallbladder occurred in 5 to 15 minutes. Sincalide reduced gallbladder radiographic size by at least 40%, which is generally considered satisfactory contraction.

**13 NONCLINICAL TOXICOLOGY**

**13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term studies in animals have not been performed to evaluate carcinogenic or mutagenic potential, or possible impairment of fertility in males or females.

**16 HOW SUPPLIED/STORAGE AND HANDLING**

Sincalide for Injection is supplied as 5 mcg of sincalide as a lyophilized white powder for reconstitution in a single-dose vial; in packages of 10 vials as follows:

Product Code	Unit of Sale	Strength	Each
579105	NDC 63323-579-05 Unit of 10	5 mcg per vial	NDC 63323-579-01 Single-Dose Vial

Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F) [See USP Controlled Room Temperature].

**17 PATIENT COUNSELING INFORMATION**

Anaphylaxis, Anaphylactic Shock and Other Serious Hypersensitivity Reactions

Inform patients that serious hypersensitivity reactions, including anaphylaxis and anaphylactic shock have been reported during or following administration of Sincalide for Injection. Advise patients to report immediately to a healthcare provider if they experience symptoms of a hypersensitivity reaction [see Warnings and Precautions (5.1)].

Gastrointestinal Adverse Reactions

Advise patients that Sincalide for Injection may cause transient gastrointestinal symptoms [see Warnings and Precautions (5.3)].

Pregnancy

Advise pregnant women of the potential risk for preterm labor and spontaneous abortion [see Warnings and Precautions (5.4), Use in Specific Populations (8.1)].

**Rx only**

Manufactured by:



Lake Zurich, IL 60047  
www.fresenius-kabi.com/us