KINEVAC[®] (Sincalide for Injection)

Indications

KINEVAC[®] (Sincalide for Injection), is indicated in adults 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
- stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology
- 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

IMPORTANT SAFETY INFORMATION

Contraindications

KINEVAC is contraindicated in patients with a history of hypersensitivity to sincalide, including anaphylaxis and anaphylactic shock, or in patients with intestinal obstruction.

Warnings and Precautions

Post-marketing **anaphylaxis**, **anaphylactic shock**, **and other serious hypersensitivity reactions** have been reported during and within one hour following administration of Kinevac. If anaphylaxis or other hypersensitivity reactions occur, immediately discontinue the infusion and initiate appropriate medical treatment.

Stimulation of gallbladder contraction can lead to **small gallbladder stone evacuation**, resulting in lodging in the cystic duct or in the common bile duct.

Kinevac may cause adverse reactions such as **nausea**, **vomiting**, **abdominal pain or cramping**, **dizziness**, **and flushing**. To reduce the risk of adverse reactions, administer Kinevac over 50 minutes for simulation of gallbladder contraction or over 30 minutes to accelerate transit of a barium meal through the small intestine.

Pregnant patients should be advised that Kinevac can effect smooth muscle, which may cause spontaneous abortion or premature induction of labor.

The most common adverse reactions (\geq 20%) include abdominal discomfort or pain, and nausea.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

Please click <u>here</u> to see the accompanying full Prescribing Information for Kinevac (Sincalide for Injection).

Kinevac is manufactured for Bracco Diagnostics Inc., Princeton, NJ 08540, by Fresenius Kabi USA, LLC, Spokane, WA 99207.

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