



**FRESENIUS
KABI**

caring for life

Sincalide for Injection

First-to-Market Authorized Generic of Kinevac^{®*}

Providing You with Choice and Value



*Kinevac is a registered trademark of Bracco Diagnostics Inc.



Sincalide for Injection

First-to-Market Authorized Generic of Kinevac®*

Fresenius Kabi's Sincalide for Injection is the first-to-market authorized generic of Kinevac®. Sincalide for Injection meets the same quality standards as the branded product, while providing you with choice and value.

Sincalide for Injection is a diagnostic aid used to help diagnose certain problems of the gallbladder and pancreas. Sincalide is also used to speed up the transit of a barium meal, a contrast agent, given in preparation for x-ray examination of the intestines.¹

Authorized generic medicines are the same high quality as their brand-name versions.²

The FDA ensures an authorized generic medication provides the same clinical benefit and has the same safety and efficacy profile as the brand-name medicine.

An **authorized generic** drug is the same as the brand-name drug but does not use the brand name on the label. An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug.²

Authorized generic and brand-name medicines have the same:



ACTIVE
INGREDIENTS



SAFETY



EFFECTIVENESS



STRENGTH



QUALITY



BENEFITS

To learn more about authorized generic drugs visit www.FDA.gov.

INDICATIONS

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

Sincalide for Injection 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 sincalide. 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.

Sincalide may cause adverse reactions such as nausea, vomiting, abdominal pain or cramping, dizziness, and flushing. To reduce the risk of adverse reactions, administer sincalide 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 sincalide 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 www.fda.gov/medwatch or call 1-800-FDA-1088.

Please [click here](#) for full Prescribing Information for Sincalide for Injection.

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Sources:

1. Sincalide for Injection Prescribing Information, October 2022

2. FDA Authorized Generic Drugs, updated 10/01/22 <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>

Sincalide for Injection

Authorized Generic of Kinevac®*

	Brand-Name Drug	Authorized Generic	Equivalent
Name	Kinevac® ¹	Sincalide for Injection ²	
Description	Kinevac (sincalide for injection) is a cholecystopancreatic-gastrointestinal hormone for parenteral administration. The agent is a synthetically-prepared C-terminal octapeptide of cholecystokinin.	Sincalide for Injection is a cholecystopancreatic-gastrointestinal hormone for parenteral administration. The agent is a synthetically-prepared C-terminal octapeptide of cholecystokinin.	✓
Indication	<p>Kinevac is a cholecystokinin (CCK) analog indicated in adults to:</p> <ul style="list-style-type: none"> 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 in combination 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. 	<p>Sincalide for Injection is a cholecystokinin (CCK) analog indicated in adults to:</p> <ul style="list-style-type: none"> 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 in combination 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. 	✓
Features	Sterile, nonpyrogenic, lyophilized white powder. No preservative is added.	Sterile, nonpyrogenic, lyophilized white powder. No preservative is added.	✓
Strength	5 mcg per vial	5 mcg per vial	✓
Ingredients	<p>Active Ingredient: 5 mcg sincalide</p> <p>Inactive Ingredients: 30 mg arginine hydrochloride, 15 mg lysine hydrochloride, 170 mg mannitol, 4 mg methionine, 2 mg pentetic acid, 0.005 mcg polysorbate 20, 9 mg potassium phosphate dibasic, and 0.04 mg sodium metabisulfite.</p>	<p>Active Ingredient: 5 mcg sincalide</p> <p>Inactive Ingredients: 30 mg arginine hydrochloride, 15 mg lysine hydrochloride, 170 mg mannitol, 4 mg methionine, 2 mg pentetic acid, 0.005 mcg polysorbate 20, 9 mg potassium phosphate dibasic, and 0.04 mg sodium metabisulfite.</p>	✓
Vial Presentation	Single-Dose Vial	Single-Dose Vial	✓
Storage	Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F)	Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F)	✓

Please see Important Safety Information on page 2.

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1. Kinevac Prescribing Information, August 2019

2. Sincalide for Injection Prescribing Information, October 2022



Sincalide for Injection

- **First-to-Market Authorized Generic of Kinevac®***
- **Preservative Free**
- **Container closure is not made with natural rubber latex**

Unit of Sale NDC	Description	Strength	Unit of Sale
63323-579-05	Single-Dose Vial	5 mcg per vial	10

Please see Important Safety Information on page 2.

Ordering Information

Please contact your account representative or our Customer Service Department Monday through Friday, 7:00AM - 6:00PM (CST) at:

Toll-Free: (888) 386-1300

Fax: (800) 743-7082

E-mail: customerservice.usa@fresenius-kabi.com

For more information visit: GenericContrastAgents.com

If you are interested in establishing a new account with Fresenius Kabi USA, contact us for additional information and necessary forms.

A Cost-Effective Option from an Experienced, Reliable Supplier

Committed to Helping You

Fresenius Kabi is a global health care leader that is doing More in America. We are dedicated to putting essential medicines and technologies in the hands of people who care for patients. In fact, more than 70% of our products for the U.S. are proudly formulated, filled and packaged right here in America.¹ Our ongoing commitment to more supply, science and support in America is one of the reasons our customers can deliver patient care with more confidence. As a leading provider of generic medications, we leverage our 100-year history to deliver innovative therapies that are safe, effective and affordable.

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Sources:
1. 2022 data on file.