Physicians' Desk Reference

For Radiology and Nuclear Medicine

PDR®

1977/8

Publisher: CHARLES E. BAKER JR.
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ISBN 0-87489-986-9

Squibb & Sons—Cont.

within 24 hours. Any residual Sinografin within the uterine cavity is usually expelled immediately upon removal of the cannula.

Storage

Store at room temperature (20–25° C.) and protect against exposure to strong light. The Sinografin solution may vary in color from essentially colorless to light amber; however, solutions which have become strongly discolored should not be used. Sinografin should be used as promptly as possible following withdrawal into the syringe, and the syringe should be rinsed as soon as possible after injection, to prevent freezing of the plunger.

How Supplied

In single-dose vials of 10 ml.

SQUIBB CONTRAST AGENT ADJUNCT

KINEVAC®

℞

(Sincalide for Injection)

Description

Kinevac (Sincalide for Injection) is a sterile, lyophilized, white powder of the synthetic C-terminal octapeptide of cholecystokinin. Each vial provides 5 mcg. sincalide with 45 mg. sodium chloride as a carrier; sodium hydroxide or hydrochloric acid may be added during manufacture to adjust the pH to 5.5 to 6.5. When reconstituted with 5 ml. of Sterile Water for Injection U.S.P. each ml. contains 1 mcg. sincalide and 9 mg. sodium chloride. At the time of manufacture, the air in the vial is replaced by nitrogen.

Actions

When injected intravenously, sincalide produces a substantial reduction in gallbladder size by causing this organ to contract. The evacuation of bile that results is similar to that which occurs physiologically in response to endogenous cholecystokinin. The intravenous (bolus) administration of sincalide causes a prompt contraction of the gallbladder that becomes maximal in 5 to 15 minutes, as compared with the stimulus of a fatty meal which causes a progressive contraction that becomes maximal after approximately 40 minutes. Generally, a 40 percent reduction in radiographic area of the gallbladder is considered satisfactory contraction.

Like cholecystokinin, sincalide, when given in conjunction with secretin stimulates pancreatic secretion; concurrent administration increases the volume of pancreatic secretion and the output of bicarbonate and protein (enzymes) by the gland. This combined effect of secretin and sincalide permits the assessment of specific pancreatic function through measurement and analysis of the duodenal aspirate. The parameters usually determined are: volume of the secretion; bicarbonate concentration; and amylase content (which parallels the content of trypsin and total protein).

Indications

Kinevac (Sincalide for Injection) is a diagnostic agent which may be used: (1) to provide a sample of gallbladder bile that may be aspirated from the duodenum for analysis of its composition, e.g., to determine the degree of cholesterol saturation, (2) in conjunction with secretin (see DOSAGE AND ADMINISTRATION) to stimulate pancreatic secretion for analysis of its composition and examination of cytology, e.g., in suspected cancer of the pancreas, (3) for postevacuation cholecystography, where the physician deems this procedure indicated but wishes to avoid the fatty meal.

Contraindications

The preparation is contraindicated in patients sensitive to sincalide.

Warnings

Usage in Pregnancy: Although no teratogenic or antifertility effects were seen in animal studies, data are inadequate to determine the safety of sincalide in human pregnancy. Accordingly, sincalide should be used in pregnant women only when, in the judgment of the physician, the benefits outweigh the possible risk to the fetus.

Usage in Children: The safety of sincalide for use in children has not been established.

Precautions

The possibility exists that stimulation of gallbladder contraction in patients with small gallbladder stones could lead to the evacuation of the stones from the gallbladder, resulting in their lodging in the cystic duct or in the common bile duct. The risk of such an event is considered to be minimal because sincalide, when given as directed, does not ordinarily cause complete contraction of the gallbladder.

Adverse Reactions

Gastrointestinal symptoms such as abdominal discomfort or pain, and an urge to defecate, frequently accompany the injection of sincalide. These phenomena are usually manifestations of the physiologic action of the drug, which include delayed gastric emptying and increased intestinal motility, and are not to be construed as necessarily indicating an abnormality of the biliary tract unless there is other clinical or radiologic evidence of disease. Nausea, dizziness, and flushing occur occasionally.

Dosage and 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. When Kinevac (Sincalide for Injection) is used in cholecystography, roentgenograms are usually taken at five-minute intervals after the injection. For visualization of the cystic duct, it may be necessary to take roentgenograms at one-minute intervals during the first five minutes after the injection.

For the Secretin-Kinevac test of pancreatic function, the patient receives a dose of 0.25 units secretin per kg. infused intravenously over a 60-minute period. Thirty minutes after the initiation of the secretin infusion, a separate I.V. infusion of Kinevac (Sincalide for Injection) at a total dose of 0.02 mcg. per kg. is administered over a 30-minute interval. For example, the total dose for a 70 kg. patient is 1.4 mcg. of sincalide; therefore, dilute 1.4 ml. of reconstituted Kinevac solution to 30 ml. with Sodium Chloride Injection U.S.P. and administer at a rate of 1 ml. per minute.

Reconstitution and Storage

Kinevac (Sincalide for Injection) may be stored at room temperature prior to reconstitution. To reconstitute, aseptically add 5 ml. of Sterile Water for Injection U.S.P. to the vial; the solution may be kept at room temperature and should be used within 24 hours of reconstitution, after which time any unused portion should be discarded.

How Supplied

In vials containing 5 mcg. of sincalide.

MEDOTOPES®
SQUIBB RADIOPHARMACEUTICALS

ANGIOTENSIN I IMMUTOPE® KIT

For Quantitative Measurement of Plasma Renin Activity by Radioimmunoassay
For *In Vitro* Diagnostic Use
For Professional Use Only

The Angiotensin I IMMUTOPE KIT is intended for the determination of plasma renin activity by radioimmunoassay.

The Angiotensin I IMMUTOPE Kit contains sufficient materials for 200 tubes. Each kit contains 1 bottle of ^{125}I Angiotensin I Buffer (200 ml., with a total activity of less than 1.7 microcuries, containing a buffer, protein carrier, and preservative); 6 vials of Angiotensin I Standard (2 ml. each; 0 pg., 50 pg., 100 pg., 200 pg., 300 pg., and 500 pg., containing a carrier and solvent); 1 vial of Angiotensin I Antiserum (10 ml., containing stabilizers, and an agent for pH adjustment); 1 vial of Angiotensin I Control (2 ml., containing a sheep serum diluent, microbial inhibitor, and enzyme inhibitors); 1 vial of Angiotensin I Adsorbent Charcoal Tablets (210 tablets, containing fillers, buffers, and an excipient); 1 vial of Angiotensin I Plasma Buffer (5 ml., with a pH of 7.4, containing fillers, buffers, and an excipient); 1 vial of Dimercaprol Solution (2 ml., containing a stabilizer and solvent); and 1 vial of 8-Hydroxyquinoline Sulfate (330 mg.).

In addition to the complete kit described above, ^{125}I Angiotensin I Buffer, Angiotensin I Standard, Angiotensin I Antiserum, and Angiotensin I Control can be purchased individually.

Digoxin CLASP™ RIA Kit

For Quantitative Measurement of Serum or Plasma Digoxin Levels by Radioimmunoassay
For *IN VITRO* Diagnostic Use
For Professional Use Only

The Digoxin CLASP RIA Kit is intended for the quantitative measurement of serum or plasma digoxin levels by radioimmunoassay.

The Digoxin CLASP RIA Kit is available in a 100-tube package. Each kit contains 5 vials of ^{125}I Digoxigenin (lyophilized, with a total activity of less than 0.45 microcurie per vial and containing buffers, a carrier, and a preservative); 6 bottles of Digoxin Standard (1 ml. each; 0 ng., 0.5 ng., 1.0 ng., 2.0 ng., 3.0 ng., and 5.0 ng. with a preservative); 100 Digoxin Antibody Coated Tubes (with a binding agent); and 1 bottle of Digoxin Control (1 ml. in sheep serum with a preservative).

GASTRIN IMMUTOPE® KIT

For *In Vitro* Diagnostic Use
For Quantitative Measurement of Serum Gastrin Levels by Radioimmunoassay

The Gastrin IMMUTOPE Kit for the measurement of serum gastrin levels by radioimmunoassay is available in a 100-test package. The kit contains one vial of ^{125}I Gastrin, one vial of Gastrin Standard A, one vial of Gastrin Standard B, one vial of Gastrin Antiserum, one vial of Barbital Buffer Mixture, one vial of Egg Albumin Powder, and one vial of Ion Exchange Resin.

MACROTEC®

℞

(Aggregated Albumin)

Description

Macrotec is a sterile, nonpyrogenic, lyophilized preparation of aggregated albumin. Each vial of Macrotec contains 0.08 mg. tin as chloride, 1.5 mg. denatured human serum albumin, and 10 mg. Normal Human Serum Albumin with trace amounts of sodium acetate, acetic acid, and hydrochloric acid; contains no preservative.

Macrotec was prepared from blood that was nonreactive when tested for hepatitis B surface antigen (HB_sAg).

Reconstitution of Macrotec (Aggregated Albumin) with sterile sodium pertechnetate-^{99m}Tc forms an aqueous suspension of Technetated (Tc-99m) Aggregated Albumin (Human) (^{99m}Tc-MAA).

Physical Characteristics

Technetium ^{99m}Tc decays by isomeric transition with a physical half-life of 6.03 hours.[1] The principal photon that is useful for detection and imaging studies is listed in Table I.