For examinations of the colon, the patient should be given a low solid diet for a minimum of 24 hours before the examination. Laxatives should also be used to clean the colon. In order to obtain thorough cleansing of the colon, a 2 liter water enema one hour before the examination may be necessary.

**Administration**

Orally administered suspension may be served chilled for more rapid transit from the stomach into the small bowel. Rectally administered suspension should be at room temperature to body temperature.

**Suspension Preparation**

Mix Tonopaque and water vigorously. For accurate suspension preparation, measure the water and the Tonopaque separately.

Prepared suspension may be used for up to 72 hours if stored in a tightly closed container and refrigerated.

**Remix prior to use.**

The following tables will serve as a guide for suspension preparation.

### TONOPAQUE DILUTION TABLE

<table>
<thead>
<tr>
<th>Suspension Concentration</th>
<th>% w/w:</th>
<th>100</th>
<th>80</th>
<th>68</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water required to prepare suspension in mLs:</td>
<td>% w/v:</td>
<td>60</td>
<td>50</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>180 gm</td>
<td>120</td>
<td>180</td>
<td>220</td>
<td>270</td>
<td></td>
</tr>
<tr>
<td>1200 gm</td>
<td>800</td>
<td>1200</td>
<td>1465</td>
<td>1800</td>
<td></td>
</tr>
</tbody>
</table>

Tonopaque™ suspensions may be prepared using the volume marks on the bottle. First add 800 mL water (27 fl. oz.) to the bottle, cap and shake vigorously for 30 seconds. For optimum suspension quality, allow to stand for 5 minutes, then add water to the desired volume (see table below for final concentrations) and mix.

### COMPARISON (% w/v vs. % w/w vs. specific gravity)

<table>
<thead>
<tr>
<th>% w/v:</th>
<th>100</th>
<th>80</th>
<th>68</th>
<th>60</th>
</tr>
</thead>
<tbody>
<tr>
<td>% w/w:</td>
<td>60</td>
<td>50</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.80</td>
<td>1.67</td>
<td>1.59</td>
<td>1.50</td>
</tr>
</tbody>
</table>

**Pediatric Use**

The quantity of suspension used and the barium sulfate concentration will depend upon patient size, technique used and clinical need.

Shake well before using. Use within 72 hours of preparation.

**HOW SUPPLIED**

Catalog No. 179606. NDC 68240-223-36. 180 gm bottle; thirty-six (36) bottles with straws per case.

Catalog No. 139542. Tonojug. NDC 68240-22608. 1200 gm per bottle; eight (8) bottles per case.

Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59° to 86°F).

Tonopaque and Tonojug are trademarks of Lafayette Pharmaceuticals, Incorporated.

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**LAFAYETTE**

**TONOPAQUE**

**BARIUM SULFATE FOR SUSPENSION**

Rx only

**DESCRIPTION**

Tonopaque is a cherry flavored barium sulfate formulation for use as a contrast medium during x-ray diagnosis of the gastrointestinal tract. An aqueous suspension of the product is to be prepared at the time of administration.

The contrast medium contains 95% barium sulfate (meets USP specifications except bulkiness), sorbitol, suspending agents, potassium sorbate, simethicone, flavoring and saccharin sodium. Barium sulfate has the empirical formula of BaSO\(_4\).

**CLINICAL PHARMACOLOGY**

Barium sulfate is an insoluble material which, because of its density, provides a positive contrast during x-ray examination. Barium sulfate is an inert radiopaque material which is not absorbed or metabolized and is eliminated intact from the body in a manner similar to other non-absorbed inorganic materials. Excretion rate is a function of gastrointestinal transit time.

**INDICATIONS AND USAGE**

Tonopaque is indicated for use as a contrast medium in x-ray diagnosis of the gastrointestinal tract.

**CONTRAINDICATIONS**

Barium sulfate products are contraindicated in patients with known or suspected obstruction of the colon, known or suspected gastrointestinal tract perforation, suspected tracheoesophageal fistula, obstructing lesions of the small intestine, pyloric stenosis, inflammation or neoplastic lesions of the rectum, recent rectal biopsy, or known hypersensitivity to barium sulfate formulations.

Barium sulfate suspensions should not be used for infants with swallowing disorders or for newborns with complete duodenal or jejunal obstruction or when distal small bowel or colon obstruction is suspected. Barium sulfate suspension is not recommended for very small preterm infants and young babies requiring small volumes of contrast media or for infants and young children when there is a possibility of leakage from the gastrointestinal tract, such as necrotizing enterocolitis, unexplained pneumoperitoneum, gasless abdomen, other bowel perforation, esophageal perforation or post operative anastomosis.

Known hypersensitivity or allergy to latex is a contraindication for the use of balloon retention enema tips containing latex. The use of a retention cuff enema tip is not necessary or desirable in patients with normal sphincter tone. The presence of adequate sphincter tone can be judged by preliminary rectal digital examination.

**WARNINGS**

Serious adverse reactions, including death, have been reported with the administration of barium sulfate formulations and are usually associated with the technique of administration, the underlying pathological condition and/or patient hypersensitivities.

Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis. Oral administration of barium sulfate suspension by an infant sucking a bottle and administration of large quantities by catheter are reported to be likely to result in aspiration...
into the tracheobronchial tree. Cardiopulmonary arrest leading to fatality has been reported in infants following aspiration. Aspiration of smaller amounts may cause inflammation.

Barium sulfate preparations used as radiopaque media contain a number of additives to provide diagnostic properties and patient palatability. Allergic responses following the use of barium sulfate suspensions have been reported. Skin irritation, redness, inflammation and hives have been reported for infants and small children following spillage of barium sulfate suspension on their skin. These responses are thought to be caused by the flavors and/or preservatives used in the product.

Barium sulfate suspension has been reported to cause obstruction of the small bowel (impaction) in pediatric patients with cystic fibrosis. It has also been reported to cause fluid overload from the absorption of water during studies in infants when Hirschsprung’s Disease is suspected.

Barium sulfate suspension intravasation can be a serious complication. Mortality has been reported as a result of vaginal or rectal intravasation and is believed to be due to massive pulmonary embolism occurring within minutes of the inciting event.

In patients with increased cranial pressure, barium sulfate suspension enemas present an additional risk of further increasing intracranial pressure.

Care must be taken during the insertion of an enema tip into the patient to prevent application of pressure to the vagus nerve which can lead to vasovagal reactions and syncopal episodes. Cardiac arrhythmia or other cardiovascular side effects can occur as a result of colon distention.

**PRECAUTIONS**

**General**

Diagnostic procedures which involve the use of radiopaque contrast agents should be carried out under the direction of personnel with the requisite training and with a thorough knowledge of the particular procedure to be performed. A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, a family history of allergy, or a previous reaction to a contrast agent warrant special attention. Caution should be exercised with the use of radiopaque media in severely debilitated patients and in those with marked hypertension or advanced cardiac disease.

Anaphylactic and allergic reactions have been reported during double contrast examinations in which glucagon has been used.

An increased risk of perforation has been reported in neonates with intussusception. In patients with cystic fibrosis or blind loops of the bowel or ileus, there is a risk of inspissation leading to partial or complete obstruction.

In neonates and infants with motility disorders such as Hirschsprung’s Disease retention of large amounts of barium sulfate suspension may result in absorption of water from the suspension and fluid overload. The addition of small amounts of salt to the barium sulfate suspension has been reported to reduce the problem.

Ingestion of barium sulfate suspension is not recommended in patients with a history of food aspiration. If barium sulfate suspension is aspirated into the larynx, further administration of the suspension should be immediately discontinued.

Patient preparation for diagnostic gastrointestinal examinations frequently requires cathartics and a liquid diet. The various preparations can result in water loss for the patient. Patients should be rehydrated quickly following a barium sulfate suspension examination of the gastrointestinal tract. In patients with reduced colon motility, saline cathartics may be required after the barium sulfate suspension enema. Saline cathartics are recommended on a routine basis in patients with a history of constipation unless clinically contraindicated.

Where enema tips are used, care must be taken during insertion into the patient, since forceful or too deep insertion may cause tearing or perforation of the rectum. Insertion of an enema tip should be done only after digital examination by qualified medical personnel. When balloon retention tips are used, care should be taken to avoid overinflation of the balloon, since overfilling or asymmetrical filling may cause displacement of the tip. Such a displacement can lead to rectal perforation or barium sulfate granulomas. Inflation of the balloon should be done under fluoroscopic control by qualified medical personnel. Do not unnecessarily move the enema tip once inserted.

A specially designed enema tip is required for a barium sulfate suspension examination of a colostomy patient.

Intubation of an enteroclysis catheter should be done by qualified medical personnel. Perforation of the duodenum has been reported.

Because of reported anaphylactoid reactions to latex, the use of non-latex gloves during the procedure should be considered.

**Pregnancy**

Safe use of barium sulfate during pregnancy has not been established. Barium sulfate should be used in pregnant women only if the possible benefits outweigh the potential risks. Elective radiography of the abdomen is considered to be contraindicated during pregnancy due to the risk to the fetus from radiation exposure. Radiation is known to cause harm to the unborn fetus exposed in utero.

**Pediatric Use**

The radiographic contrast agents used for examination of children do not differ substantially from those used for adults. The variation in physical sizes of pediatric patients requires more thorough attention to individualizing dosage. The volume of barium sulfate suspension and the barium sulfate content required will also depend upon the technique used and the clinical need.

**ADVERSE REACTIONS**

Adverse reactions accompanying the use of barium sulfate formulations are infrequent and usually mild, though severe reactions (approximately 1 in 500,000) and fatalities (approximately 1 in 2,000,000) have occurred. Procedural complications are rare, but may include aspiration pneumonitis, barium sulfate impaction, granuloma formation, intravasation, embolization and peritonitis following intestinal perforation, vasovagal and syncopal episodes, and fatalities. EKG changes have been shown to occur following or during barium sulfate suspension enemas. It is of the utmost importance to be completely prepared to treat any such occurrence.

Due to the increased likelihood of allergic reactions in atopic patients, a complete history of known and suspected allergies as well as allergic-like symptoms, such as rhinitis, bronchial asthma, eczema and urticaria, must be obtained prior to any medical procedure.

Aspiration of large amounts of barium sulfate suspension may cause pneumonitis or nodular granulomas of interstitial lung tissues and lymph nodes; asphyxiation and death have been reported.

Transient bacteremia, beginning almost immediately and lasting up to 15 minutes, may also occur during rectal administration of barium sulfate suspension, and rarely septicemia has been reported.

A rare mild allergic reaction would most likely be generalized pruritis, erythema or urticaria (approximately 1 in 100,000 reactions). Such reactions will respond to an antihistamine such as 50 mg (adult dosage) of diphenhydramine or its equivalent. More serious reactions (approximately 1 in 500,000) may result in laryngeal edema, bronchospasm or hypotension.

Severe reactions which may require emergency measures are often characterized by peripheral vasodilation, hypotension, reflex tachycardia, dyspnea, agitation, confusion and cyanosis, progressing to unconsciousness. Treatment should be initiated immediately with 0.3-0.5 cc (adult dosage) of 1:1000 epinephrine subcutaneously. If bronchospasm predominates, 0.25-0.50 grams (adult dosage) of intravenous aminophylline should be given slowly. Appropriate vasopressors might be required. Adrenocorticosteroids, even if given intravenously, exert no significant effect on the acute allergic reaction for a few hours. The administration of these steroid agents should not be regarded as emergency measures for the treatment of allergic reactions.

Apprehensive patients may develop weakness, pallor, tinnitus, diaphoresis and bradycardia following the administration of any diagnostic agent. Such reactions are usually non-allergic in nature and are best treated by having the patient lie flat for an additional 10 to 30 minutes and under observation.

Allergic reactions to the enema accessories, in particular to retention catheters (tips) with latex cuffs, can occur. Such reactions could occur immediately and result in the previously mentioned acute allergic-like responses or might be delayed in appearance and result in a contact dermatitis. Known atopic patients, particularly those with a history of asthma or eczema, should be evaluated for alternative methods of administration in order to avoid these adverse reactions. These plastic/rubber accessories are disposable, single-use devices that must not be reused or left in the body cavity for an extended period of time.

**OVERDOSE**

In rare instances, immediate repeat oral examinations utilizing standard dosages may lead to severe stomach cramps and diarrhea. Cases reported in adults implicate a total dose in the range of 30 ounces (900 mL) of suspension. Instances of this type have resolved spontaneously and they are not considered to be life-threatening.

**DOSAGE AND ADMINISTRATION**

Individual technique will determine the suspension quantity and concentration to be used.

**Patient Preparation**

Successful examination of the upper gastrointestinal tract requires that the stomach be empty and essentially free of fluid. This can usually be accomplished by instructing the patient to abstain from eating or drinking anything after the evening meal before the examination. The preparation for small bowel examinations done separately or combined with an upper gastrointestinal series is the same.