ENTROBAR (Barium Sulfate Suspension)

Dosage and Administration: Individual technique will determine the suspension quantity and barium sulfate content to be used. Undiluted Entrobar may be used for a "dedicated" small bowel follow-through examination or when performing the "biphasic" enteroclysis technique. Entrocel™ (methylcellulose solution) may be used for the second phase of the biphasic examination.

Dilute Entrobar to the desired density when performing single contrast enteroclysis.

% BARIUM SULFATE (w/v) ENTROBAR WATER TO BE ADDED
50% 500 mL Use undiluted
45% 500 mL 55 mL
40% 500 mL 125 mL
35% 500 mL 215 mL
30% 500 mL 355 mL

Shake the suspension well before using.

The basic principles for intubation and infusion, as published in the medical literature, should be followed for a faster and more diagnostic examination.

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

How Supplied: Catalog No. 153218. 500 mL bottles. Twelve (12) per case.

Related products for enteroclysis examinations:
Entrokit: Catalog No. 153580. Enteroclysis examination kit containing 500 mL Entrobar, 500 mL Entrocel and administration materials. Four (4) kits per case.
Entrokit with Catheter: Catalog No. 153504. Enteroclysis examination kit containing 500 mL Entrobar, 500 mL Entrocel, administration materials and enteroclysis catheter. Four (4) kits per case.
Entrobag Set: Catalog No. 153180. Enteroclysis administration set containing two 3 liter bags, Y connector and luer adapter tubing. Six (6) sets per case.
Enteroclysis Catheter: Catalog No. 153404. Sterile 155 cm x 13 French enteroclysis catheter with retention balloon and guide wire. One (1) per case.
Decompression/Enteroclysis Catheter: Catalog No. 153408. Sterile 155 cm x 14 French decompression/enteroclysis catheter with retention balloon and guide wire. One (1) per case.

Rx only

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

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Made in Mexico
Manufactured by:
Mallinckrodt Inc.
St. Louis, MO 63042 USA
www.Mallinckrodt.com

Rx only
ENTROBAR (Barium Sulfate Suspension)

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 anastomoses.

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.

Precautions: 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 warrants 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.

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. Effective 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. 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 septicaemia has been reported.

A rare mild allergic reaction would most likely be generalized pruritus, 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 1.000 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 under observation.

Overdosage: In rare instances, immediate repeat oral examina-