NDC 69307-1024-2

SILQ™

BARIUM SULFATE SUSPENSION (2.1% w/v)

DESCRIPTION: SILQ™ is a barium sulfate suspension 2.1% w/v, 2.0% w/w for oral administration. Each 100 mL contains 2.1 g barium sulfate. Barium sulfate, due to its high molecular density is opaque to x-rays and therefore, acts as a positive contrast agent for radiographic studies. The active ingredient is barium sulfate and its structural formula is $BaSO_4$. Barium sulfate occurs as a fine, white, odorless, tasteless, bulky powder which is free from grittiness. Its aqueous suspensions are neutral to litmus. It is practically insoluble in water solutions of acids and alkalies, and organic solvents.

Inactive Ingredients: citric acid, natural and artificial flavors, benzoic acid, suspending agent, potassium sorbate, purified water, sodium saccharin, sodium citrate, simethicone, sodium benzoate, sorbitol

CLINICAL PHARMACOLOGY: Barium sulfate, due to its high molecular density is opaque to x-rays and, therefore, acts as a positive contrast agent for radiographic studies. Barium sulfate is biologically inert and, therefore, is not absorbed or metabolized by the body, and is eliminated from the GI tract unchanged. Excretion rate is a function of gastrointestinal transit time.

INDICATIONS AND USAGE: For use as a contrast agent in radiographic studies.

CONTRAINDICATIONS: This product should not be used in patients with known or suspected gastric or intestinal perforation, or hypersensitivity to barium sulfate or any component of this barium sulfate formulation; in patients with known or suspected obstruction of the colon; suspected tracheoesophageal fistula; obstructing lesions of the small intestine; pyloric stenosis; inflammation or neoplastic lesions of the rectum; or in patients who have had a recent rectal biopsy.

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 nectrotizing enterocolitis, unexplained pneumoperitoneum, gasless abdomen, other bowel perforation, esophageal perforation or post operative anastomosis.

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.

PRECAUTIONS: General: 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, or a previous reaction to a contrast agent, warrant special attention. Caution should be exercised with the use of radiopaque media in severly debilitated patients and in those with marked hypertension or advanced cardiac disease. Ingestion of barium is not recommended in patients with a history of food aspiration or in patients in whom the integrity of the swallowing mechanism is unknown. If barium is aspirated into the larynx, further administration should be immediately discontinued. After any barium study of the GI tract, it may be important to rehydrate the patient as quickly as possible to prevent impaction of the barium. To prevent barium impaction in the colon, the use of mild laxatives such as milk of magnesia or lactulose following completion of the examination may also be required. These mild laxatives are recommended on a routine basis and in patients with a history of constipation unless clinically contraindicated.

Hypersensitivity Reactions: Barium sulfate preparations contain a number of excipients, including natural and artificial flavors and may induce serious hypersensitivity reactions. The manifestations include hypotension, bronchospasm, and other respiratory impairments, dermal reactions including rashes, urticarial, and itching. A history of bronchial asthma, atopy, or a previous reaction to a contrast agent may increase the risk for hypersensitivity reactions. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.

Intra-abdominal Barium Leakage: The use of Vanilla SilQ products is contraindicated in patients at high risk of perforation of the GI tract. Administration of Vanilla SilQ products may result in leakage of barium for the GI tract in the presence of conditions such as carcinomas, GI fistula, inflammatory bowel disease, gastric or duodenal ulcer, appendicitis, or diverticulitis, and in patients with a sever stenosis at any level of the GI tract, especially if it is distal to the stomach. The barium leakage has been associated with peritonitis and granuloma formation.

Delayed Gastrointestinal Transit and Obstruction: Orally administered barium sulfate may accumulate proximal to a constricting lesion of the colon, causing obstruction or impaction with development of baroliths (inspissated barium associated with feces) and may lead to abdominal pain, appendicitis, bowel obstruction, or rarely perforation. Patients with the following conditions are at higher risk for developing obstruction or baroliths: severe stenosis at any level of the GI tract, impaired GI motility, electrolyte imbalance, dehydration, on a low residue diet, taking medications that delay GI motility, and constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration following a barium sulfate procedure.

Aspiration Pneumonitis: The use of Vanilla SilQ products is contraindicated in patients at high risk of aspiration. Oral administration of barium is associated with aspiration pneumonitis, especially in patients with a history of food aspiration or with compromised swallowing mechanism. Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis. In patients at risk for aspiration, begin the procedure with a small ingested volume of Vanilla SilQ products. Discontinue administration of Vanilla SilQ products immediately of aspiration is suspected.

Systemic Embolization: Barium sulfate products may occasionally intravasate into the venous drainage of the large bowel and enter the circulation as a "barium embolus" leading to the potentially fatal complications which include systemic and pulmonary embolism, disseminated intravascular coagulation, septicemia and prolonged severe hypotension. Although this complication is exceedingly uncommon after oral administration of barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

Risk with Hereditary Fructose Intolerance: Vanilla SilQ contains sorbitol which may cause sever reactions if ingested by patients with hereditary fructose intolerance such as vomiting, hypoglycemia, jaundice, hemorrhage, hepatomegaly, hyperuricemia, and kidney failure. Before administration of Vanilla SilQ assess patients for a history of hereditary fructose intolerance and avoid use in these patients.

Information for Patients: Before using this product patients should be instructed to tell the physician ordering the procedure and the imaging technologist:

1. if they are pregnant.
2. if they are allergic to any foods or medication, or if they have had any prior reactions to barium sulfate products or other x-ray contrast agents.
3. if they are currently taking any medications, have any serious medical condition for which they are being treated or followed, or had any recent surgery.
4. Seek immediate medical attention if they experience an allergic or other adverse reaction during or after use of this product.

Drug Interactions: The presence of barium sulfate formulations in the GI tract may alter the absorption of therapeutic agents taken concomitantly. In order to minimize any potential change in absorption, the separate administration of barium sulfate from that of other agents should be considered.

Usage in Pregnancy: Radiation is known to cause harm to the unborn fetus exposed *in utero*. Therefore, radiographic procedures should only be used when, in the judgment of the physician, its use is deemed essential to the welfare of the pregnant patient.

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, e.g. 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 often respond to an antihistamine. 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, bronchospasm, agitation, confusion and cyanosis, progressing to unconsciousness. Treatment should be initiated immediately according to established standard of care.

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.

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.

OVERDOSAGE: On rare occasions following repeated administration, severe stomach cramps, nausea, vomiting, diarrhea or constipation may occur. These are transitory in nature and are not considered serious. Symptoms may be treated according to currently accepted standards of medical care.

DOSAGE AND ADMINISTRATION: Barium sulfate volume and method of administration are determined by individual technique, and may vary with differing patient and procedure characteristics.

STORAGE: Store product to protect from freezing and excessive heat (above 40°C).

℞ **only (USA)** **SHAKE WELL PRIOR TO USE**

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