VANILLA SILQ MD- barium sulfate for suspension powder, for suspension
Genus Medical Technologies, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Vanilla SilQ MD (R)

DESCRIPTION

VANILLA SILQ MD™ is a barium sulfate for suspension 96% w/w for oral and rectal administration. Each 100 g contains 96 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

simethicone, sorbitol, saccharin sodium, natural and artificial flavor, emulsifers, and thickening agents

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, patients with conditions that may increase the risk of perforation; hypersensitivity to barium sulfate products; 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. Use caution if administering this product to 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.

Administration: Give careful consideration to the risks and benefits of the administration of a barium sulfate suspension to patients with possible gastrointestinal blockage. Take care to minimize the amount of barium allowed to flow proximal to the tissue affected with blockage or lesion. When administering this product with an enema tip, use caution to avoid insertion in a manner that is too forceful or deep, as this may cause tearing or perforation of the colorectal tissues.

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.

Patients should 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 may occur during rectal administration of barium sulfate suspension, and 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.

OVERDOSAGE

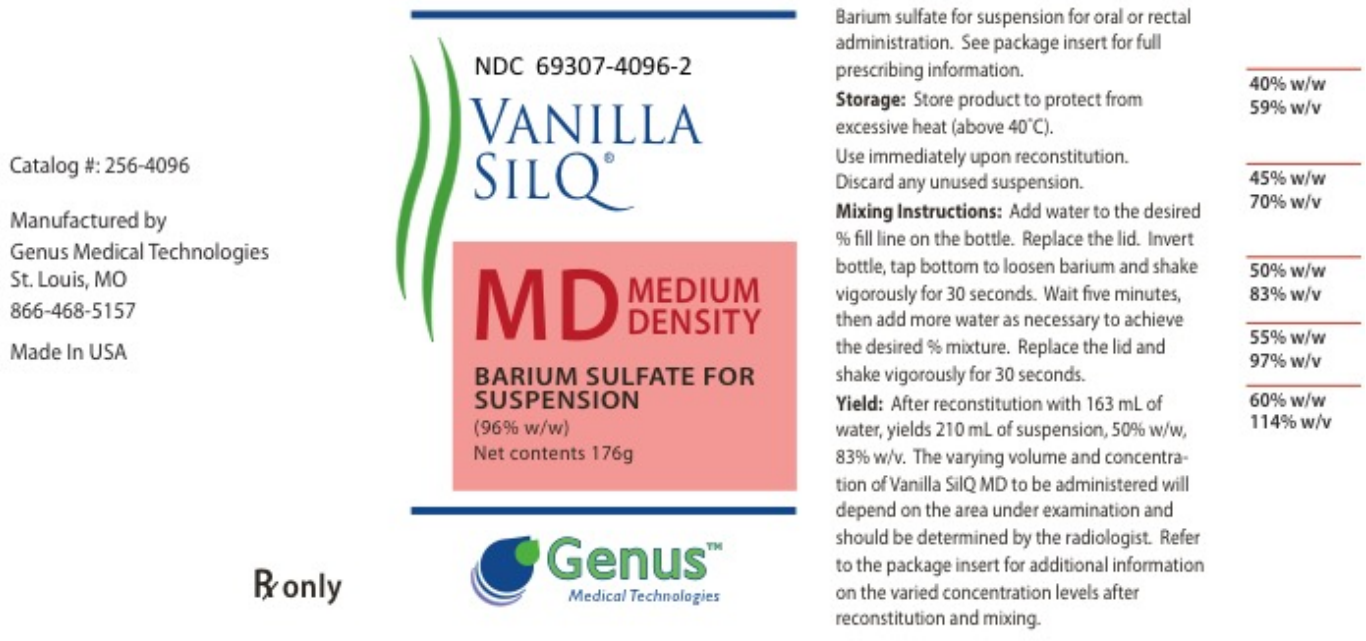
On rare occasions following repeated administrations, stomach cramps, nausea, vomiting, diarrhea or constipation may occur. Symptoms may be treated according to currently accepted standards of medical care.

DOSAGE AND ADMINISTRATION

Barium sulfate volume and method of administration are determined by individual technique, and may vary with differing patient and procedure characteristics. Add water to the desired % w/w fill line on bottle. Replace lid. Invert bottle, tap bottom to loosen barium, and shake vigorously for 30 seconds. Let stand at least 5 minutes. Add additional water as necessary to achieve the desired % mixture. Replace lid, and again shake vigorously for 30 seconds.

STORAGE

Store product to protect from excessive heat (above 40 degrees centigrade)



VANILLA SILQ MD

barium sulfate for suspension powder, for suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69307-4096
Route of Administration	RECTAL, ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Barium Sulfate (UNII: 25BB7EKE2E) (Barium Sulfate - UNII:25BB7EKE2E)	Barium Sulfate	96 g in 100 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69307-4096-2	176 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2015	

Labeler - Genus Medical Technologies, LLC (079478547)

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