

**VANILLA SILQ HD- 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 HD**

**DESCRIPTION**

**VANILLA SILQ HD™** is a barium sulfate for suspension 98% w/w for oral and rectal administration. Each 100 g contains 98 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<sub>4</sub>. 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 alkalis, and organic solvents.

**INACTIVE INGREDIENTS**

simethicone, sorbitol, saccharin sodium, natural and artificial vanilla flavor, emulsifiers, 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.

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

**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 severely 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.

## **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.

To report suspected adverse reactions to FDA call 1-800-332-1088. To report to Genus Medical Technologies, call 1-866-468-5157.

## **STORAGE**

Store product to protect from excessive heat (above 40°C).

## **OVERDOSAGE**

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

## **INDICATIONS AND USAGE**

For use as a contrast agent in radiographic studies.

## 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 67 mL of water to create a 135mL suspension with a density of 225% w/v (81% w/w). After adding water, 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.

## 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.

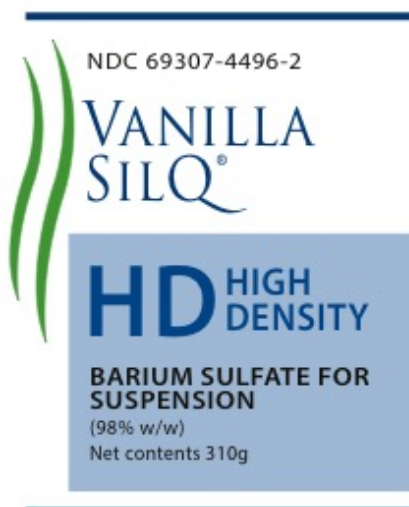
Catalog #: 256-4496

Manufactured by  
Genus Medical Technologies  
St. Louis, MO  
866-468-5157

Made In USA



Rx only



Barium sulfate for suspension for oral administration. See package insert for full prescribing information.

**Storage:** Store product to protect from excessive heat (above 40°C).

Use immediately upon reconstitution. Discard any unused suspension.

**Mixing Instructions:** Add 67mL water to the Vanilla SilQ HD bottle and replace lid securely. Invert bottle, tap bottom to loosen barium and shake vigorously for 30 seconds. Wait 5 minutes, then shake thoroughly.

**Yield:** After reconstitution with 67mL of water, yields 135mL of suspension, 81% w/w, 225% w/v.

## VANILLA SILQ HD

barium sulfate for suspension powder, for suspension

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69307-4496
<b>Route of Administration</b>	ORAL, RECTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
BARIUM SULFATE (UNII: 25BB7EKE2E) (BARIUM SULFATE - UNII:25BB7EKE2E)	BARIUM SULFATE	98 g in 100 g

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69307-4496-2	310 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/09/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2015	

**Labeler** - Genus Medical Technologies, LLC (079478547)

Revised: 1/2021

Genus Medical Technologies, LLC