Voyageur SmoothHD™ Prescribing Information – Canada

Voyageur SmoothHD™ (BARIUM SULFATE) FOR ORAL SUSPENSION, 105% w/v

Note to practitioners: In Canada, the Voyageur SmoothHD barium sulfate oral suspension is regulated by the Natural and Non-prescription Health Products Directorate of Health Canada. For the convenience of practitioners familiar with contrast agents that are regulated as drugs, this information is provided in the typical Prescribing Information format.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use SmoothHD safely and effectively. See full prescribing information for SmoothHD.

SmoothHD (barium sulfate) oral suspension

Health Canada Natural Product Number: 80109788

----------RECENT MAJOR CHANGES----------

First Version Issued 05/2024

----------INDICATIONS AND USAGE----------

SmoothHD, a radiographic contrast agent, is indicated for use in single or double-contrast radiographic examinations of the esophagus, stomach, and small bowel to visualize the gastrointestinal (GI) tract in adult and pediatric patients (1)

----------DOSAGE AND ADMINISTRATION-------

- Adults: Recommended oral dose is between 60 – 750 mL (2.1))
- Pediatric patients: adjust reconstituted dose based on relative GI volume (2.1)

-------DOSAGE FORMS AND STRENGTHS-------

For oral suspension: 472.5 grams of barium sulfate (105% w/v) (3)

----------CONTRAINDICATIONS----------

- Known or suspected perforation of the GI tract (4)
- Known obstruction of the GI tract (4)
- Conditions associated to high risk of GI aspiration (4)
- Conditions associated to high risk of GI perforation (4)
- Known hypersensitivity to barium sulfate or any of the excipients of SmoothHD (4)

----------WARNINGS AND PRECAUTIONS-------

- Emergency equipment and trained personnel should be immediately available for treatment of a serious hypersensitivity reaction (5.1)
- Intra-abdominal leakage: Caution is recommended in patient conditions like GI fistula, ulcer, inflammatory bowel disease, appendicitis or diverticulitis, severe stenosis or obstructing lesions of the GI tract (5.2)
- Patients should maintain adequate hydration in days following a barium sulfate procedure to avoid obstruction or impaction caused by baroliths (5.3)
- Aspiration pneumonitis: Caution is recommended in patients with history of food aspiration and in patients with known swallowing disorders (5.4)

----------ADVERSE REACTIONS----------

Common adverse reactions include nausea, vomiting, diarrhea and abdominal cramping (6)

To report SUSPECTED ADVERSE REACTIONS, contact Voyageur Pharmaceuticals Ltd. at 1-877-398-6866 or Health Canada at 1-888-234-2345 or https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/natural-health-products.html

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 05/2024

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FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

SmoothHD, a radiographic contrast agent, is indicated for use in single contrast radiographic examinations of the esophagus, stomach, and small bowel to visualize the gastrointestinal tract (GI) in adult and pediatric patients.

2. DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

The optimal oral dose of SmoothHD will vary depending on the size and anatomy of the patient and the procedure being performed. The recommended oral dose of SmoothHD:

Adults:

- Esophagus and Cardiac Examinations: Undiluted SmoothHD should be administered orally for double-contrast examination of the esophagus. Images are taken during rapid swallowing of barium sulfate.
  - Typical adult dose: 60 mL to 300 mL
- Stomach: SmoothHD can be used for single or double-contrast examination of the stomach. It can be used undiluted or diluted 1:1 with water to produce a 52.5% w/v. Diluted SmoothHD is highly suited for a biphasic examination of the stomach.

  Following completion of the double-contrast examination of the stomach using VisionHD barium sulfate, SmoothHD (either undiluted or diluted 1:1 with water) may be used for the single phase of the study.
  - Typical adult dose: 150 mL to 340 mL of diluted or undiluted as applicable
- Small Bowel Series: SmoothHD® can be used for small bowel series. It can be given alone or can be used following the completion of a double-contrast examination of the stomach using VisionHD™. It may be given either undiluted or in 1:1 dilution. Higher dilution will decrease the density of the barium sulfate but will increase the speed of the flow of contrast.
  - Typical Adult Dose: 340 mL to 750 mL of diluted or undiluted as applicable..

Pediatric Patients: Adjust dose of SmoothHD based on GI volume.

2.2 Administration Instructions

- For oral use only
- Shake vigorously for 30 seconds prior to oral administration to fully suspend product.
- Administer undiluted
- Ensure patients have nothing by mouth for the following time period prior to the examination:
  - Neonates and Infants < 3 months 2 hours
  - Infants 3-12 months 3 hours
  - > 12 months of age 4 hours
- Discard any unused suspension
- Advise patients to hydrate following the barium sulfate procedure

3 DOSAGE FORMS AND STRENGTHS

For oral suspension: 472.5 grams of barium sulfate (105% w/v) in a single-dose bottle

4 CONTRAINDICATIONS

SmoothHD is contraindicated in patients:

- Known or suspected perforation of the GI tract
- Known obstruction of the GI tract
- At high risk of GI perforation such as those with a recent prior GI perforation, acute GI hemorrhage or ischemia, toxic megacolon, severe ileus, post GI surgery or biopsy, acute GI injury or burn, or recent radiotherapy to the pelvis.
- At high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation
- With known severe hypersensitivity to barium sulfate or any of the SmoothHD excipients

5 WARNINGS AND PRECAUTIONS

5.1 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, urticaria, 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.

5.2 Intra-abdominal Barium Leakage

The use of SmoothHD is contraindicated in patients at high risk of perforation of the GI tract *[see Contraindications (4)]*. Administration of SmoothHD may result in leakage of barium from 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 severe 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.

5.3 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, constipation, pediatric patients with cystic fibrosis or Hirschsprung disease, and the elderly *[see Use in Specific Populations (8.4, 8.5)]*. To reduce the risk of delayed GI transit and obstruction, patients should maintain adequate hydration during and in the days following a barium sulfate procedure. Consider the administration of laxatives.

5.4 Aspiration Pneumonitis

The use of SmoothHD is contraindicated in patients at high risk of aspiration *[see Contraindications (4)]*. 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 SmoothHD. Discontinue administration of SmoothHD immediately if aspiration is suspected.

5.5 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 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 a barium sulfate suspension, monitor patients for potential intravasation when administering barium sulfate.

5.6 Risk with Hereditary Fructose Intolerance

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

6 ADVERSE REACTIONS

The following adverse reactions have been identified from spontaneous reporting or clinical studies of barium sulfate administered orally. Because the reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure.

- Nausea, vomiting, diarrhea and abdominal cramping
- Serious adverse reactions and fatalities include aspiration pneumonitis, barium sulfate impaction, intestinal perforation with consequent peritonitis and granuloma formation, vasovagal and syncopal episodes

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

SmoothHD is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug (see Clinical Pharmacology 12.3).

8.2 Lactation

Risk Summary

SmoothHD is not absorbed systemically by the mother following oral administration, and breastfeeding is not expected to result in exposure of the infant to SmoothHD (see Clinical Pharmacology 12.3).

8.4 Pediatric Use

The efficacy of Liquid E-Z-PAQUE in pediatric patients from birth to less than 17 years of age is based on successful opacification of the esophagus, stomach, and small bowel during single contrast radiographic procedures (see Clinical Pharmacology 12.1). Safety and dosing recommendations in pediatric patients are based on clinical experience (see Dosage and Administration 2.1).

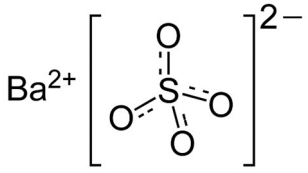
SmoothHD is contraindicated in pediatric patients with tracheo-esophageal fistula (*see Contraindications 4)*. Pediatric patients with a history of asthma or food allergies may be at increased risk for development of hypersensitivity reactions *(see Warnings and Precautions 5.1)*. Pediatric patients with cystic fibrosis or Hirschsprung disease should be monitored for bowel obstruction after use (*see Warnings and Precautions 5.3)*.

8.5 Geriatric Use

Clinical studies of SmoothHD did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

11 DESCRIPTION

SmoothHD barium sulfate) is a radiographic contrast agent that is supplied as a fine, white to lightly colored barium sulfate suspension (60 % w/v) for oral administration. The active ingredient barium sulfate is designated chemically as BaSO4 with a molecular weight of 233.43 g/mol, a density of 4.5 g/cm3, and the following chemical structure:



SmoothHD contains excipients including: Xanthan Gum, Simethicone, Potassium Sorbate, Sodium Benzoate, Sodium Citrate, Citric Acid, Gum Arabic, Carrageenan, Sorbitol, Sodium Saccharin, and Vanilla Flavouring.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Due to its high atomic number, barium (the active ingredient in SmoothHD) is opaque to x-rays and therefore acts as a positive contrast agent for radiographic studies.

12.3 Pharmacokinetics

Under physiological conditions, barium sulfate passes through the GI tract in an unchanged form and is absorbed only in pharmacologically insignificant amounts.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No animal studies have been performed to evaluate the carcinogenic potential of barium sulfate or potential effects on fertility.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

SmoothHD (barium sulfate), is supplied in a single-dose HDPE plastic bottle containing 472.5 grams of barium sulfate (105% w/v).

Provided as: 12 bottles per pack

16.2 Storage and Handling

Store at controlled room temperature. Protect from freezing.

17 PATIENT COUNSELING INFORMATION

After administration advise patients to:

- Maintain adequate hydration
- Seek medical attention for worsening of constipation or slow gastrointestinal passage
- Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty

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