Berlin

Package insert

Barimac

Barium sulfate powder for oral suspension

1. Product Name

Barimac

2. Name and strength of Active Ingredient

Barimac : Barium sulfate powder for oral suspension 30% w/v of Barium Sulfate (after reconstitution). Net contents 7.4 g (Equivalent to 6 g Barium Sulfate) per 20 mL bottle.

3. Product Description

Powder for oral suspension

Barimac : Fine, white to creamy white powder

4. Pharmacodynamics/Pharmacokinetics

Mechanism of Action

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

Pharmacodynamics

Barium sulfate is biologically inert and has no known pharmacological effects.

Pharmacokinetics

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

5. Indications

Barium sulfate is a radiographic contrast agent indicated in adult patients for use in computed tomography (CT) colonography as a fecal tagging agent.

6. Recommended Doses

The recommended oral dose of Barimac is one 20 mL bottle (6 g barium sulfate) with each meal (breakfast, lunch and dinner) the day before the colonography examination. Total dose = 3 bottles (18 g barium sulfate).

7. Mode of Administration

Oral suspension: barium sulfate (30% w/v) supplied as a ready-to-use suspension in a 20 mL, single-dose, plastic bottle for oral administration. Each 20 mL bottle contains 6 g of barium sulfate.

Pediatric Use

Barimac is not indicated for pediatric use.

Important Administration Instructions

- Barium sulfate is typically provided to the patient for self-administration. Advice patients to carefully read and follow the Patient Instructions for use to be provided to the patient.
- Shake bottle for 15 seconds prior to administration.
- For oral use only.
- Encourage patients to hydrate following the barium sulfate procedure.
- Discard any unused suspension

8. Contraindications

Barimac is contraindicated in patients with:

- known or suspected perforation of the gastrointestinal (GI) tract;
- known obstruction of the GI tract;
- high risk of GI perforation such as those with a recent 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;
- high risk of aspiration such as those with prior aspiration, tracheo-esophageal fistula, or obtundation;
- known hypersensitivity to barium sulfate or any of the excipients of Barimac

9. Warnings and Precautions

- **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 (evidenced by hay fever and eczema), 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 Barimac is contraindicated in patients at high risk of perforation of the GI tract. Administration of Barimac may result in leakage of barium from the GI tract in the presence of conditions that increase the risk of perforation 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 gastrointestinal 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 gastrointestinal motility, electrolyte imbalance, dehydration, on a low residue diet, on medications that delay GI motility, constipation, cystic fibrosis, 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 Barimac 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.

- **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 barium sulfate products, monitor patients for potential intravasation when administering barium sulfate.

- Concomitant use of other oral agents; separate oral administration.
- Care is needed in those with lesions that may predispose to obstruction.
- Blind loops of the bowel or ileus; risk of inspissation leading to partial or complete obstruction.
- Marked hypertension
- Advanced cardiac disease
- History of constipation; routine saline cathartics are recommended unless clinically contraindicated. Reduced colon motility, post-procedure saline cathartics may be required.
- Severely debilitated patients
- Increased cranial pressure; risk of exacerbation.
- Severe reactions (i.e., vomiting, jaundice, hypoglycemia, hepatomegaly, hemorrhage, kidney failure, and hyperuricemia) may occur in patients with hereditary fructose intolerance; avoid use.

10. Interactions with Other Medicaments

No interaction studies have been performed.

Barium sulfate is biologically inert and there are no known interactions with other medicinal product. However, the presence of barium sulfate formulations in the gastrointestinal tract may alter the absorption of therapeutic agent taken concomitantly. In order to minimise any potential change in absorption, the separate administration of barium sulfate from that of other medicines should be considered.

11. Pregnancy and Lactation

- **Pregnancy**

  Risk Summary

  Barimac is not absorbed systemically following oral administration, and maternal use is not expected to result in fetal exposure to the drug.

- **Lactation**

  Risk Summary

  Barimac is not absorbed systemically by the mother following oral administration and breastfeeding is not expected to result in exposure of the infant to the drug.

12. Undesirable Effects

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:

- Common adverse reaction include 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.

Nonclinical Pharmacology

- **Carcinogenesis, Mutagenesis, Impairment of Fertility**

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

13. Overdose and Treatment

Overdose

Barium sulfate is non-toxic and absorbed systemically in negligible amount.
Repeated use within a very short period of time has led to abdominal cramps, nausea, vomiting, diarrhea and constipation. These symptoms are transitory in nature and may be allowed to resolve without medical intervention or may be treated according to currently accepted standards of care.

14. Storage Condition

Store below 30°C

15. Dosage Forms Available and Packaging

Powder for oral suspension
Plastic bottle 20 mL

16. Name and address of Manufacturer

Manufacturer: Berlin Pharmaceutical Industry Co., Ltd.
222 Romklao Road, Kongsamprawet, Ladkrabang, Bangkok
For further information: Tel. 0-2252-4650-7 Fax. 0-2252-4658

17. Date of Revision of Package Insert

13 February 2019