# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

BariCat 49.2 mg/ml concentrate for oral suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 225ml of undiluted suspension contains 11.07g of barium sulfate (49.2 mg/ml).

Excipients :
Each dose of 225 ml undiluted suspension contains 16 g sorbitol (E420) (as sorbitol, liquid (crystallising)).
Each dose of 225 ml of undiluted suspension contains 110.25mg of methyl parahydroxybenzoate (E218).
Each dose of 225 ml of undiluted suspension contains approximately 206 mg of sodium.
Each dose of 225 ml of undiluted suspension contains approximately 50 mg of potassium.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Concentrate for oral suspension.

A white viscous, aqueous suspension with a sweet orange flavour, without grittiness.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

BariCat should be used, following dilution as instructed, to opacify the gastro-intestinal tract prior to computerised axial tomography.

### 4.2 Posology and method of administration

For oral administration.

The concentrate is diluted with water to obtain a desired concentration.
Recommended dilutions are shown in section 6.6.

Adults including the elderly: 350 - 450 ml of diluted suspension 30 minutes prior to the scan and the same volume 5 minutes prior to the scan, or as directed by the physician.

Children: The quantity of BariCat given should be determined, from experience, by the physician and will be dependent on the age and weight of the child.

### 4.3 Contraindications

*Immune System Disorders*

Hypersensitivity to barium sulfate or to any of the excipients.

*Gastrointestinal Disorders*

Patients with any of the following :

- a known or suspected fistula, perforation or obstruction in any part of the gastrointestinal tract
- gastrointestinal haemorrhage
- gastrointestinal ischaemia
- megacolon or toxic megacolon
- necrotising enterocolitis
- severe constipation
- severe impaired gastric emptying

must not receive BariCat.

BariCat must not be used for infants with swallowing disorders.

*Surgical and Medical Procedures*

Barium sulfate must not be administered immediately before or immediately after gastrointestinal surgery, including snare polypectomy or 'hot' colonic biopsy. If post procedural leakage is expected the product must not be used. Do not use during and up to four weeks after radiotherapy to the rectum or prostate.

*Injury, Poisoning and Procedural Complications*

Do not use if there are new injuries or chemical burns of the gastrointestinal tract.

## 4.4 Special warnings and precautions for use

This product should be administered under the supervision of a physician.

Diagnostic 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.

*Hypersensitivity*

A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, a family history of allergy, or a previous reaction to a contrast agent warrant special attention.

As stated in section 4.8, 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. Anaphylactic and allergic reactions have been reported during double contrast examinations in which glucagon has been used. Rapid recognition, assessment, and diagnosis are crucial to the effective implementation of treatment. Imaging facilities should be staffed with well-trained personnel for the diagnosis and treatment of hypersensitivity reactions.

*Perforation*

In patients with a serious stenosis at any level of the gastro-intestinal tract, especially if it is distal to the stomach, and in the presence of conditions and ailments that increase the risk of perforation such as carcinomas, inflammatory intestinal disease, diverticulitis and diverticulosis and amoebiasis, careful consideration of the risks and benefits of the administration of a barium sulfate suspension is required.

*Aspiration*

For patients who are prone to aspiration (the newborn, elderly and stroke patients), it is recommended that the procedure starts with a small ingested volume.

Vomiting following oral administration of barium sulfate may lead to aspiration pneumonitis. Oral administration of barium sulfate suspension by an infant sucking a bottle and administration of large quantities by catheter are reported to be likely to result in aspiration into the tracheobronchial tree. Cardiopulmonary arrest leading to fatality has been reported in infants following aspiration. Aspiration of smaller amounts may cause respiratory tract inflammation and pneumonia.

Ingestion of barium is not recommended in patients with a history of food aspiration. If barium procedures are required in these patients or in patients in whom integrity of the swallowing mechanism may be compromised, proceed with caution. If this product is aspirated into the larynx, further adminstration should be immediately discontinued.

*Fluid Overload*

Barium sulfate suspensions have been reported to cause fluid overload due to water absorption.

Children and patients with impaired renal function are the most susceptible to water intoxification, as are children with Hirschsprung's Disease.

It is suggested to not fill the entire colon when evaluating a child with Hirschsprung's Disease; use only the amount of fluid necessary for the diagnosis.

Preparatory enemas in patients with Hirschsprung's Disease should be avoided.

*Intravasation*

Barium sulfate may also intravasate into the venous drainage of the large bowel and enter the circulation as a "barium embolus". This complication occurs rarely, but can lead to potentially fatal complication, including systemic and pulmonary embolism, disseminated intravascular coagulation, septicaemia and prolonged severe hypotension. It is more likely to occur in elderly patients, due to thinning of the rectal wall and vaginal thinning with age, and in those with colorectal disease, when intraluminal pressure overcomes the resistance of the colonic wall affected by colitis, diverticulitis or intestinal obstruction. The diagnosis should be considered in any patient who collapses during or shortly after a barium procedure, and in those who become suddenly unwell in the hours following the procedure. The diagnosis can be confirmed by simple plain radiography; CT scanning may also be useful to detect dissemination of barium sulfate.

*Constipation or Diarrhoea*

BariCat should be used with care if the patient is dehydrated, suffers from any condition or is on any other treatment that can cause constipation, or if the patient has history of constipation. In this situation a mild bulk laxative should be administered following completion of the X-ray examination. Increased intake of liquids is recommended after oral or rectal administration of barium sulfate to prevent severe constipation and the risk of impaction.

Conversely, since BariCat contains sorbitol, administration may have a mild laxative effect. The calorific value of sorbitol is 2.6 kcal/g.

*Other Possible Complications*

Apprehensive patients may develop weakness, pallor, tinnitus, diaphoresis and bradycardia following the administration of any diagnostic agent. Such reactions are usually unpredictable and are best treated by having the patient lie flat for an additional 10-30 minutes under observation.

Patient preparation for diagnostic gastrointestinal examinations frequently requires cathartics and a liquid diet. The various preparations can result in water loss for the patient. Patients should be rehydrated quickly following a barium sulfate suspension examination of the gastrointestinal tract. Saline cathartics are recommended on a routine basis in patients with a history of constipation unless clinically contraindicated.

*Baroliths*

Baroliths consist of inspissated barium associated with faeces. They are often asymptomatic, but may be associated with abdominal pain, appendicitis, bowel obstruction or perforation. Patients who are elderly, with impaired gastrointestinal motility, colon obstruction, electrolyte imbalance, dehydration or on a low residue diet may be at risk of developing baroliths. To reduce this risk, adequate hydration should be maintained during and in the days following barium sulfate procedure. The use of laxatives (especially in case of constipation) should be considered.

*Hereditary Fructose Intolerance*

BariCat contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not use this medicine. Therefore, it should only be used in babies and small children after consultation with the doctor, due to the possibility of unknown hereditary fructose intolerance.

*Patients on a Controlled Sodium or Potassium Diet*

BariCat contains approximately 206 mg sodium per dose of 225 ml undiluted suspension. Care should be taken in patients on a controlled sodium diet, especially in the cases of repeated administration.

It also contains approximately 50 mg potassium per dose of 225 ml undiluted suspension. Care should be taken with patients who have reduced kidney function or those on a controlled potassium diet.

*Other Excipients*

BariCat contains methyl parahydroxybenzoate (E218), which may cause allergic reactions, sometimes delayed.

*Children, Elderly and Debilitated Patients*

As with any barium sulfate preparation, care should be taken when administering BariCat to children, the elderly or the debilitated.

## 4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Barium sulfate is biologically inert and there are no known interactions with other medicinal products. However, the presence of barium sulfate formulations in the gastrointestinal tract may alter the absorption of therapeutic agents 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.

Other examinations of the same area of the gastrointestinal tract with another contrast agent may be complicated by the presence of barium sulfate (residue) in the gastrointestinal tract up to several days following the examination with barium contrast media.

## 4.6 Fertility, pregnancy and lactation

*Pregnancy*

There is no data from the use of barium sulfate in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Because barium sulfate is not absorbed by the digestive tract, BariCat can be used during pregnancy. However, it is stressed that radiographic procedures may damage the foetus, particularly during the first trimester of pregnancy. Any examination should only be carried out after careful consideration of the benefit/risk of the procedure.

*Lactation*

Since barium sulfate is not absorbed, BariCat can be used during breast-feeding.

## 4.7 Effects on ability to drive and use machines

BariCat has no known effect on the ability to drive and use machines.

## 4.8 Undesirable effects

Undesirable effects may occur during or after a procedure with barium sulfate.

Skin and subcutaneous disorders together with immune system disorders, reflecting allergic reactions either to barium sulfate or the product excipients, are among the most commonly reported effects; for example urticaria, erythema and rash.

Gastrointestinal disorders are also one of the most frequently reported class of undesirable effects; for example diarrhoea, nausea, abdominal pain/distention, constipation. Gastrointestinal signs and symptoms are widely reported, it is not always possible to differentiate between pre-existing medical conditions and procedural complications.

Hypersensitivity presenting with a wide range of signs and symptoms including skin and subcutaneous reactions such as urticaria, pruritus, rash, erythema and facial swelling has been reported. Potential hypersensitivity associated respiratory signs and symptoms including dyspnoea, pharyngeal oedema and throat tightness have also been reported.

Within the table below, clinically significant adverse reactions are listed if they have been reported post authorisation of all barium sulfate formulations, and have not been reported in clinical trials. Their frequency is not known (cannot be estimated from the available data).

| **MedDRA System Organ Class** | **MedDRA Preferred Term** |
|---|---|
| Infections and infestations | Appendicitis, Bacteraemia, Abscess intestinal, Liver abscess, Peritoneal infection and Pneumonia. |
| Blood and the lymphatic system disorders | Lymphadenopathy |
| Immune system disorders | Hypersensitivity, Anaphylactic reaction and anaphylactic shock. |
| Metabolism and nutrition disorders | Hyperglycaemia (in diabetic patients) |
| Psychiatric disorders | Agitation, Confusional state, Nervousness. |
| Nervous system disorders | Loss of consciousness, Syncope, Syncope vasovagal, Dizziness, Burning sensation, Headache, Dysarthria, Hypotonia. |
| Eye disorders * | Eye disorders, including Eye swelling. |
| Ear and labyrinth disorders | Tinnitus. |
| Cardiac disorders | Bradycardia, Cyanosis, Tachycardia. |
| Vascular disorders | Hypotension, Pallor, Vasodilatation. |
| Respiratory, thoracic and mediastinal disorders | Bronchospasm, Dyspnoea, Laryngeal oedema, Pharyngeal oedema and pain, Throat irritation or tightness, Cough. When administered orally, Aspiration, Pneumonia aspiration. |
| Gastrointestinal disorders | Constipation and in severe cases gastrointestinal blockage;<br>Gastrointestinal inflammation, ulceration or perforation; Abdominal discomfort, Abdominal pain and distension; Diarrhoea; Colitis ulcerative may be aggravated; Nausea; Vomiting and Retching; Flatulence; Swollen tongue. |

| | |
|---|---|
| Skin and subcutaneous tissue disorders * | Erythema, Dermatitis Contact, Excessive granulation tissue, Hyperhidrosis, Periorbital oedema, Pruritus, Rash, Swelling face, Urticaria. |
| Renal and urinary disorders | Dysuria. |
| General disorders and administration site conditions | Malaise, Pain, Swelling, Asthenia, Pyrexia, Face oedema. |
| Investigations | Electrocardiogram abnormal. |
| Injury and poisoning | Intravasation by barium sulfate, associated with pre-existing bowel disease or diverticulitis. |

*These reactions are associated with allergic reactions.

More rarely and depending on the route of administration, i.e. oral or rectal, the following procedural complications have been reported : Infections (e.g. peritonitis) subsequent to existing or new gastrointestinal perforation. Complications include adhesions and granuloma. Subsequent to existing or procedural gastrointestinal trauma, intravasation of barium sulfate with rare subsequent venous emboli formation, including the hepatic portal vein, vena cava and pulmonary embolism that may be fatal in approx 50% of cases.

Following oral administration, aspiration, with pulmonary complications, may occur and may be fatal in rare cases.

Please see section 4.4 for measures to be taken to avoid these adverse reactions, and actions to take if such adverse reactions occur.

Very rare cases of death associated with barium sulfate administration have been reported in the literature. The majority of the deaths relate to procedural complications usually caused by failure to follow generally accepted radiological practice. Some cases had a history indicating that barium sulfate administration was highly unlikely to be a primary or even secondary causative factor in patient fatality.

## 4.9 Overdose

Barium sulfate is non toxic and not absorbed.

Repeated use within a very short period of time has led to abdominal cramps, nausea, vomiting, diarrhoea 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.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: X-ray contrast media, barium sulfate with suspending agents, ATC Code: VO8BA01

Barium Sulfate itself has no pharmacological effects. It serves only to opacify the gastro-intestinal tract during computerised axial tomography.

## 5.2 Pharmacokinetic properties

Not applicable. Barium sulfate, the active constituent of BariCat is not absorbed from the gastrointestinal tract.

## 5.3 Preclinical safety data

There are no preclinical data considered relevant to clinical safety beyond data included in other sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sorbitol, liquid (crystallising) (E420)
Pectin (E440)
Xanthan gum (E415)
Simeticone emulsion 30%
Sodium citrate (E331)
Citric acid anhydrous (E330)
Potassium sorbate (E202)
Methyl parahydroxybenzoate (E218)
Artificial orange flavour [including natural and artificial flavours and butylated hydroxyanisole (E320)]
Saccharin sodium (E954)
Sodium carrageenan (E407)
Polyoxyethylene glyceryl mono-oleate
Purified water

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf life

Unopened: 2 years.

After dilution : The product should be used immediately after dilution and must not be stored.

## 6.4 Special precautions for storage

Store below 25°C. Do not freeze.

## 6.5 Nature and contents of container

High density polyethylene (HDPE) bottle with polypropylene screw-on closure and tamper evident seal containing 225 ml of the suspension.
Boxes of 1 and 24 bottles.

## 6.6 Special precautions for disposal and other handling

Do not accept if the tamper evident seal is broken.

The product should be shaken well prior to use.

The dilution instructions are provided in the package leaflet and are as follows:-

Dilution instructions:

1. Pour BariCat contents into a litre container.
   Add water to give total volume of 900 ml.

2. Shake well.

3. This will yield 900 ml of 12 mg/ml barium sulfate suspension.

4. Alternatively, BariCat may be mixed to yield a different density. Some suggestions are as follows:-

(a) Add BariCat contents into the mixing container and add water to 700 ml level. Yields 15 mg/ml suspension.

(b) Add water to the 600 ml level. Yields 18 mg/ml suspension.

(c) Add water to the 500 ml level. Yields 21 mg/ml suspension.

This product is intended for single dose use only. The product should be administered immediately following dilution and any unused product should be discarded.

Any usused, opened product or waste material should be disposed of in accordance with local requirements.

## 7 MARKETING AUTHORISATION HOLDER

Bracco UK Limited
Bracco House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Bucks HP10 0HH
United Kingdom

## 8 MARKETING AUTHORISATION NUMBER

PA 1022/16/1

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 1995
Date of last renewal: 10th March 2010

## 10 DATE OF REVISION OF THE TEXT

August 2014