

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **BariCat 49.2 mg/ml concentrate for oral suspension**

barium sulfate

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, radiographer or nurse helping you with your examination which is usually called a CT or CAT scan.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, radiographer or nurse helping you with your examination.

**In this leaflet:**

1. What BariCat is and what it is used for
2. Before you use BariCat
3. How to use BariCat
4. Possible side effects
5. How to store BariCat
6. Further information

#### **1. What BariCat is and what it is used for**

BariCat belongs to a group of medicines called 'contrast media'. It is used when you have an examination called a CT or CAT scan where X-rays are used. It contains a chemical that helps the X-ray show up.

BariCat will be given to you as a drink.

This medicine is for diagnostic use only. It only helps to diagnose a problem. It cannot be used to treat any diseases.

#### **2. Before you use BariCat**

**Do not use BariCat if you:**

- are allergic (hypersensitive) to barium sulfate or any of the other ingredients of BariCat (see section 6)
- know that you have a hole or blockage in your bowel or stomach (gastrointestinal perforation or obstruction)
- know that you have an abnormal passage connecting your stomach with your bowel (gastrointestinal fistula)

- suffer from bleeding in your bowel or stomach
- suffer from insufficient blood supply (ischaemia) of the bowel wall
- have an enlarged bowel - a condition called megacolon or toxic megacolon
- have an inflamed condition of the bowel called necrotising enterocolitis
- suffer from severe constipation
- suffer from a stomach condition called impaired gastric emptying
- are a baby and have problems swallowing
- have recently had bowel surgery, such as a procedure called ‘hot’ colonic biopsy or snare polypectomy
- have had radiotherapy (cancer treatment) to your large bowel (rectum) or prostate gland within the last 4 weeks
- have suffered recent injury to your bowel or stomach, including chemical burns.

If any of the above applies to you, do not use BariCat and talk to your doctor again.

**Take special care with BariCat if you:**

- or members of your family suffer from allergies, hay fever, eczema or asthma
- are elderly
- are feeling weak (debilitated)
- are a baby or small child
- suffer from narrowing of the bowel or stomach (stenosis)
- suffer from cancer of any part of the bowel
- suffer from inflammatory intestinal disease
- suffer from a condition known as diverticulitis where you have swelling or infection in part of your large bowel, causing you to suffer from stomach pain or cramps, fever or chills
- have a condition called diverticulosis (abnormal areas in your large bowel)
- suffer from an infection caused by amoebas (amoebiasis)
- suffer from an enlarged, blocked bowel (a condition called Hirschsprung’s Disease)
- have ever suffered from aspiration (where you might breathe in food or liquid into your lungs)
- find swallowing difficult
- have ever suffered from a stroke
- have kidney problems
- suffer from constipation
- are dehydrated.

If any of the above applies to you, talk to your doctor before you use BariCat.

**Using other medicines**

Please tell your doctor, radiographer or nurse helping you with your X-ray examination if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

BariCat may interfere with the action of other medicines taken at the same time. Your doctor may separate the administration of barium sulfate from that of your other medicines or other digestive tract examinations.

**Pregnancy and breast-feeding**

Tell the doctor or nurse if you know that you are pregnant or you are trying to become pregnant. X-rays can harm unborn babies so you will only be given an X-ray if it is essential for you.

You can continue to breast feed if you take BariCat.

**Driving and using machines**

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

**Important information about some of the ingredients of BariCat**

BariCat contains sorbitol which may have a mild laxative effect. The calorific value of sorbitol is 2.6 kcal/g. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

It also contains approximately 206 mg sodium per 225 ml dose of undiluted suspension. To be taken into consideration by patients on a controlled sodium diet.

BariCat also contains approximately 50 mg potassium per 225 ml dose of undiluted suspension. To be taken into consideration by patients with reduced renal function or patients on a controlled potassium diet.

It also contains methyl parahydroxybenzoate (E218) that can cause allergic reactions, possibly delayed.

Ask your doctor if one of the above warnings is applicable to you, or has been in the past.

### **3. How to use BariCat**

**Adults, the elderly and children:** Your doctor determines how much BariCat is used.

BariCat will be given to you as a drink.

If you are dehydrated, prone to suffering from constipation or elderly you may be offered a laxative before you use BariCat.

After your examination, you may be given a drink, laxative or put on a saline drip.

### **4. Possible side effects**

Like all medicines, BariCat can cause side effects, although not everybody gets them.

**Seek immediate medical help if you have any of the following symptoms:**

- **feeling faint or loss of consciousness**
- **swelling of the face or throat**
- **difficulty in breathing or wheezing, shortness of breath.**

These are the signs of a severe and sometimes life threatening allergic reaction, such as shock.

The following side effects can also develop when you are given this type of medicine:

#### **Skin problems:**

- itching
- inflammation (hot, red or swollen skin)
- redness
- rash
- sweating
- pale, clammy skin
- skin turning a blue or purple colour due to poor circulation.

#### **Stomach/bowel problems:**

- constipation
- blocked bowel (the blockage would have to be removed by a doctor)
- diarrhoea
- feeling sick or being sick (nausea, retching or vomiting)
- stomach pain or a bloated stomach
- excess wind (flatulence)
- bowel inflammation, ulceration or perforation (a hole)
- swollen tongue

- a damaged bowel wall lining which may lead to bacteria in the blood, an abscess or appendicitis. You may be given antibiotics to prevent this.
- in rare cases an enema may damage the lining of the bowel wall. When this happens, it may result in an infection of the bowel or its lining (peritonitis), or a type of swelling called 'granuloma'
- small amounts of barium sulfate may leak into the blood supply and end up in other parts of the body such as blood vessels or arteries. This occurs rarely, but the result can be very serious and may cause death.
- if you suffer from ulcerative colitis (inflammation of the bowel), BariCat may aggravate your condition.

**Heart problems:**

- changes in heart rhythm.

**Respiratory problems:**

When BariCat is taken as a drink, there is a small risk that you could breathe it in. This may lead to:

- difficulty breathing
- cough and sore throat
- pneumonia (lung infection) which can result in death. This is very rare.

**Other possible side effects:**

- high blood sugar (hyperglycaemia) in diabetics
- agitation, confusion or nervousness whilst the product is being administered.
- feeling dizzy
- swollen eyes
- tinnitus (ringing in the ears)
- low blood pressure
- problems passing urine
- feeling unwell, pain including headache, fever or feeling like you are burning
- swelling, weakness, muscle or speech problems
- swollen lymph nodes.

**If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.**

## **5. How to store BariCat**

BariCat should be kept out of the reach and sight of children.

Do not use BariCat after the expiry date which is stated on the packaging behind the word 'EXP'. The expiry date refers to the last day of that month.

Your doctor or nurse will make sure your medicine is correctly stored and disposed of.

BariCat should be stored below 25 °C. Do not freeze.

It should be used immediately after dilution and must not be stored. Your doctor or nurse should discard any unused portion.

## **6. Further information**

### **What BariCat contains**

- The active ingredient is barium sulfate 49.2 mg/ml.
- The other ingredients are sorbitol, liquid (crystallizing) (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.

### **What BariCat looks like and contents of the pack**

BariCat is a white, milky, viscous concentrate for oral suspension. It is supplied in bottles containing 225 ml BariCat, boxes of 1 and 24 bottles.

### **Marketing Authorisation Holder**

Bracco UK Limited, Wooburn Green, Buckinghamshire, HP10 0HH, UK.

### **Manufacturer responsible for batch release in the EU**

Bracco UK Limited, Wooburn Green, Buckinghamshire, HP10 0HH, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium:	Unicat 49.2 mg/ml concentraat voor orale suspensie / solution à diluer pour suspension buvable / Konzentrat zur Suspension zum Einnehmen
Denmark:	Unicat 49.2 mg/ml koncentrat til oral suspension
Finland:	Unicat 49.2 mg/ml konsentraatti oraalisuspensiota varten
Ireland:	BariCat 49.2 mg/ml Concentrate for Oral Suspension
Luxembourg:	Unicat 49.2 mg/ml solution à diluer pour suspension buvable / Konzentrat zur Suspension zum Einnehmen
Norway:	Unicat 49.2 mg/ml konsentrat til mikstur, suspensjon
Sweden:	Unicat 49.2 mg/ml koncentrat till oral suspension

**This leaflet was last approved in {MM/YYYY}.**

---

**BariCat  
49.2 mg/ml concentrate for oral suspension**

barium sulfate

**The following information is intended for medical or healthcare professionals only:**  
It supplements the information provided in the package leaflet above.

**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 ‘special precautions for disposal and other handling’ below.

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.

**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 pack is intended for single-dose use only. BariCat should be administered immediately following dilution and any unused product should be discarded.

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