

PACKAGE LEAFLET: INFORMATION FOR THE USER



Polibar®

96.5 % w/w powder for rectal suspension

barium sulfate

Read all of this leaflet carefully before you have this medicine because it contains important information for you.

- 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 X-ray examination.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

In this leaflet:

1. What Polibar is and what it is used for
2. What you need to know before you have Polibar
3. How Polibar will be given to you
4. Possible side effects
5. How to store Polibar
6. Contents of the pack and other information

1. What Polibar is and what it is used for

Polibar belongs to a group of medicines called 'contrast media'. It is used when you have an X-ray of your digestive system. It contains a chemical that helps the X-ray show up. This gives a clearer 'picture' of your digestive system on the X-ray.

Polibar will be given to you as an enema (into your back passage).

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

2. What you need to know before you have Polibar

Do not have Polibar if you:

- are allergic to barium sulfate or any of the other ingredients of this medicine (see section 6)
- know that you have a hole in your bowel (gastrointestinal perforation)
- know that you have an abnormal passage connecting your stomach with your bowel (gastrointestinal fistula)
- suffer from bleeding in your bowel
- suffer from insufficient blood supply (ischaemia) of the bowel wall
- have an enlarged bowel - a condition called megacolon or toxic megacolon
- have a severe inflamed condition of the bowel called necrotising enterocolitis
- suffer from poor movement of your bowel - a condition called colonic ileus
- 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, including chemical burns.

If any of the above applies to you, you should not be given Polibar. You should talk to your doctor again.

Talk to your doctor, pharmacist or nurse before you have Polibar 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 (stenosis)
- suffer from a condition known as 'gastro-intestinal fistulae'
- suffer from cancer of any part of the bowel
- have an abnormal passage connecting your stomach with your bowel
- suffer from inflammatory intestinal disease
- suffer from a condition known as 'diverticulitis' or 'diverticulosis'
- suffer from an infection known as 'amoebiasis'
- suffer from a condition called Hirschsprung's Disease
- have kidney problems
- suffer from constipation
- are dehydrated.

If any of the above applies to you, talk to your doctor before you have Polibar.

Please also let your doctor, radiographer or nurse know if you are allergic (hypersensitive) to latex. This is because they will wear gloves to perform X-ray examination, and some gloves or enema administering equipment are made of this material.

Other medicines and Polibar

Please tell your doctor, radiographer or nurse helping you with your X-ray examination if you are taking or have recently taken or might take any other medicines.

Polibar 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 Polibar.

Driving and using machines

Polibar may cause you to feel dizzy. If this happens to you, do not drive or use machinery until this effect has worn off.

Polibar contains 29.5 mmol (or 678 mg) sodium per 397 g pack and 42.5 mmol (976 mg) sodium per 570 g pack. To be taken into consideration by patients on a controlled sodium diet.

Polibar also contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How Polibar will be given to you

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

Polibar will be given to you as an enema (into your back passage). You will need to get into the best position for this. You may be asked to lie on your side with one knee bent to your chest. A tube will be gently inserted into your back passage (anus). The medicine will then flow into your bowel.

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

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



TX1747-5

Rev. 02/19

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96.5 % w/w powder for rectal 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

Polibar is for rectal (enema) administration. The powder must be reconstituted prior to administration (see section 'Special precautions for disposal and other handling' below).

The administered dose of Polibar will depend on the patient in question and the section of the gastrointestinal tract to be viewed.

Adults: Instructions for reconstitution are shown below but the actual administered dose should be determined, from experience, by the radiologist.

Children: The dosage will be dependent on the size, age, health state and anatomic region to be imaged of the child. Individual requirements should be determined, from experience, by the radiologist.

Elderly: There are no special dosage recommendations. The dosage should be determined, from experience, by the radiologist.

Special precautions for disposal and other handling

Adults: Polibar should be suspended over the density range of 20 - 115 % w/v (20 - 60 % w/w).

Usual Dosage Range 150 - 750 g barium sulfate in a suitable suspension.

Double contrast of the large bowel - Give as required between 60 - 115 % w/v.

4. Possible side effects

Like all medicines, Polibar 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:

Rarely (affects 1 in 1,000 to 1 in 10,000 patients):

- abdominal pain
- feeling sick or being sick

Frequency not known (cannot be estimated from the available data):

Skin problems:

- itching
- redness
- rash
- sweating
- pale, clammy skin
- skin turning a blue or purple colour due to poor circulation.

Stomach/bowel problems:

- reduced oxygen supply to the intestine (intestinal ischaemia)
- constipation
- blocked bowel (the blockage would have to be removed by a doctor)
- diarrhoea
- 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), Polibar may aggravate your condition.

Heart problems:

- changes in heart rhythm.

Respiratory problems:

- difficulty breathing
- cough and sore throat.

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
- swelling, weakness, muscle or speech problems
- swollen lymph nodes.

Adverse events in children are similar to those of adults.

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance Section - Kevin O'Malley House - Earlsfort Centre - Earlsfort Terrace - IRL - Dublin 2
Tel: +353 1 6764971 - Fax: +353 1 6762517 - Website: www.hpra.ie
e-mail : medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Polibar

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

Do not use Polibar 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.

Polibar should be stored below 25 °C.

Following reconstitution, the suspension should be used immediately, and must not be stored. Your doctor or nurse should discard any unused portion.

6. Content of the pack and other information

What Polibar contains

- The active ingredient is barium sulfate 96.5 % w/w.
- The other ingredients are sorbitol (E420), sodium citrate (E331), pectin (E440), tragacanth (E413), simeticone, polysorbate 80 (E433) and citric acid anhydrous (E330).

What Polibar looks like and contents of the pack

Polibar is a white powder for rectal suspension. It is supplied in enema bags containing 397 g, or 570 g Polibar. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer responsible for batch release in the EU

Bracco Imaging spa,
Via Egidio Folli 50, 20134 Milano, Italy

Manufacturer

Bracco Imaging S.p.A. – Bioindustrial Park -
Via Ribes, 5 – 10010 Colletterto Giacosa (TO)
Italy

If this leaflet is difficult to see or read, and you would like it in a different format, please contact Bracco UK Limited, High Wycombe, Bucks, HP13 6EQ, UK.

This leaflet was last approved in February 2019.

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Polibar® 96.5 % w/w powder for rectal suspension barium sulfate

Single contrast of the large bowel - Give as required between 20 - 40 % w/v.

Reconstitution information for use of Polibar is provided below.

Attach clamp to tubing and close. Please study the graph on the enema bag label. This shows the density range and how much water to use for each density. Measure the indicated quantity of warm (40 °C) water and add this to the bag through the red snap-cap seal. Hold the bag by the finger holes and shake vigorously for 10-20 seconds. When ready to use shake again, 10-20 seconds. Then with the thumb and forefinger pop the red ball at the bag tube junction into the bag. Run barium through the tubing - attach rectal tube. The kit is now ready.

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

 **BRACCO LABELING FILE**

SIZE: 16.5" H x 8.5" W BARCODE: TX1747-5

COUNTRY: Ireland

COLOR LEGEND

Black 

