Package leaflet: Information for the user

Maxibar™

98.45 % w/w powder for oral suspension

barium sulfate

Read all of this leaflet carefully before you start using 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, or other healthcare professionals helping you with your X-ray examination. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Maxibar is and what it is used for

Maxibar 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.

Maxibar 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. What you need to know before you use Maxibar

Do not use Maxibar 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 or stomach (gastrointestinal perforation)
- know that you have an abnormal passage connecting your esophagus (tracheo-esophageal 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
- have a severe intestinal paralysis
- 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, you should not be given Maxibar. You should talk to your doctor again.

Warnings and precautions
Talk to your doctor before you have Maxibar 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 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 ever suffered from aspiration (where you might breathe in food or liquid into your lungs)
- find swallowing difficult
- have ever suffered from a stroke
- suffer from a disease called cystic fibrosis (a disease of the mucus and sweat glands)
- have kidney problems
- suffer from constipation
- are dehydrated.

Talk to your doctor or nurse before using Maxibar.

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

Maxibar 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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before using this medicine. 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 Maxibar.

Driving and using machines
Maxibar may cause you to feel dizzy. If this happens to you, do not drive or use machinery until this effect has worn off.

Maxibar contains Sorbitol and Sodium
Maxibar contains 1.89 g of sorbitol in each dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder, in which a person cannot break down fructose, talk to your doctor before you (your child) take or receive this medicine. Sorbitol can cause gastrointestinal discomfort and mild laxative effect.

This medicinal product contains 11 mmol sodium (259 mg) per 340 g dose, which is equivalent to 13% of the recommended maximum daily dietary intake of sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

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

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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

Maxibar is recommended for oral administration. The powder must be reconstituted prior to administration (see section 'Special precautions for disposal and other handling' below).

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

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.

3. How to use Maxibar

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

Maxibar 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 Maxibar.

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

4. Possible side effects

Like all medicines, this medicine 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 10,0000 patients):
- abdominal pain
- feeling sick of 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), Maxibar may aggravate your condition.

Heart problems:
- changes in heart rhythm.

Respiratory problems:
When Maxibar 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 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
- swelling, weakness, muscle or speech problems
- swollen lymph nodes.

Adverse events in children are similar to those of adults.

Reporting of side effects
If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance - 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 Maxibar

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after 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.

Maxibar does not require any special temperature storage conditions.

Store in the original container.

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

6. Contents of the pack and other information

What Maxibar contains
- The active ingredient is barium sulfate.
- The other ingredients are sorbitol (E420), acacia gum (E414), sodium citrate (E331), simeticone, citric acid anhydrous (E330), polysorbate 80 (E433), carrageenan (E407), ethyl maltol (E637), saccharin sodium (E954), strawberry flavour powder and cherry flavour powder.

Each bottle contains 340 g powder which contains 98.45 % w/w (335 g) barium sulfate.

What Maxibar looks like and contents of the pack
Maxibar is a white powder for oral suspension. It is supplied in bottles containing 340 g Maxibar. Box of 24 bottles.

The powder is mixed with water to produce a white, fruit flavoured suspension ready for use.

Marketing Authorisation Holder and Manufacturer responsible for batch release in the EU
Bracco Imaging spa,
Via Egidio Folli 50, 20134 Milano, Italy

Manufacturer
Bracco UK Limited,
Valley Business Centre Gordon Road - High Wycombe – Buckinghamshire HP13 6EQ, UK

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 XX/XXXX.

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Special precautions for disposal and other handling

Adults: The contents of one prefilled bottle (340 g) are dispersed with 65 mL of water to produce a 250 % w/v suspension which is swallowed by the patient after a suitable gas producing agent has been administered.

On reconstitution according to the directions below, Maxibar produces a white fruit flavoured suspension free from grittiness.

Reconstitution information

Do not use if inner seal is broken or missing.

1. Add approximately 65 mL of water to the bottle.
2. Secure lid and invert bottle, tapping base with the fingers to loosen powder.
3. Shake bottle vigorously for 10-20 seconds.
4. Leave until required then re-shake vigorously for 10-20 seconds.
5. Remove lid. Patient can drink from bottle.
6. Discard any unused suspension.

Important: Once reconstituted Maxibar should be used immediately. If there is a delay, it should be re-shaken prior to use.

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