

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Maxibar 98.45% w/w powder for oral suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Barium sulfate 98.45% w/w

Excipient(s) with known effect:

Sorbitol 2 g per 340 g dose; and Sodium 259 mg per 340 g dose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral suspension.

A white to off-white bulky powder for oral suspension with a slightly sweet fruit taste, intended for suspension in water.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

'Maxibar' is for use as a radiopaque agent during X-ray visualisation of the upper gastro-intestinal tract (oesophagus, stomach and duodenum). It is designed for optimal use in double contrast X-ray examinations.

4.2 Posology and method of administration

Maxibar is recommended for oral administration.

The powder must be reconstituted prior to administration (see section 6.6).

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 in section 6.6 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.

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
- ileus

should not receive Maxibar.

Maxibar should not be used for infants with swallowing disorders.

Surgical and Medical Procedures

Barium sulfate should 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.

Barium sulfate preparations used as radiopaque media contain a number of additives to provide diagnostic properties and patient palatability. Allergic responses following the use of barium sulfate suspensions have been reported. Skin irritation, redness, inflammation and hives have been reported for infants and small children following spillage of barium sulfate suspension on their skin.

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 known 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 administration 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 intoxication, as are children with Hirschsprung's Disease.

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 complications, 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

Maxibar 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 Maxibar 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, 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

Maxibar 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 Diet

Maxibar contains sodium among the excipients. Care should be taken in patients on a controlled sodium diet, especially in the cases of repeated administration.

Children, Elderly and Debilitated Patients

As with any barium sulfate preparation, care should be taken when administering Maxibar 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

Following oral or rectal administration, barium sulfate is absorbed systemically in negligible amounts. Though barium sulfate is pharmacologically inert, no studies of its mutagenic or teratogenic potential are available.

Although this product is not contraindicated in pregnancy, we would like to point out 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.

Breastfeeding

Since the absorption of barium sulfate is negligible, its use is not contraindicated during breastfeeding.

4.7 Effects on ability to drive and use machines

Maxibar has no influence 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. It is not always possible to differentiate these from pre-existing medical conditions and procedural complications.

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.

Within the table below, clinically significant adverse reactions are listed if they have been reported during post approval use of all barium sulfate formulations.

Adults

System Organ Class	Adverse reactions Frequency not known*
Infections and infestations	Bacteraemia Abscess intestinal Liver abscess Peritoneal infection Pneumonia Appendicitis
Blood and the lymphatic system disorders	Lymphadenopathy
Immune system disorders	Anaphylactic shock Anaphylactic reaction Hypersensitivity
Metabolism and nutrition disorders	Hyperglycaemia**
Psychiatric disorders	Confusional state Agitation Nervousness
Nervous system disorders	Syncope Syncope vasovagal Loss of consciousness Dizziness Dysarthria Headache Burning sensation Hypotonia
Eye disorders	Eye swelling
Ear and labyrinth disorders	Tinnitus
Cardiac disorders	Bradycardia Tachycardia Cyanosis

Vascular disorders	Hypotension Vasodilatation Pallor
Respiratory, thoracic and mediastinal disorders	Aspiration Pneumonia aspiration Bronchospasm Dyspnoea Laryngeal oedema Pharyngeal oedema Throat tightness Oropharyngeal pain Throat irritation Cough
Gastrointestinal disorders	Intestinal ischaemia Gastrointestinal obstruction Gastrointestinal perforation Gastrointestinal ulcer Colitis ulcerative aggravated Gastrointestinal inflammation Abdominal pain Abdominal distension Abdominal discomfort Constipation Diarrhoea Vomiting Retching Nausea Swollen tongue Flatulence
Skin and subcutaneous tissue disorders	Urticaria Rash Erythema Dermatitis contact Swelling face Periorbital oedema Excessive granulation tissue Pruritus Hyperhydrosis
Renal and urinary disorders	Dysuria
General disorders and administration site conditions	Pain Pyrexia Face oedema Swelling Asthenia Malaise
Investigations	Electrocardiogram abnormal
Injury, poisoning and procedural complications	Venous intravasation *** Barium impaction

* Cannot be estimated from available data as derived from spontaneous reporting.

The most appropriate MedDRA term is used to describe a certain reaction and its symptoms and related conditions.

** Cases of hyperglycaemia have been reported in diabetic patients.

*** Venous intravasation was associated with pre-existing bowel disease or diverticulitis

Paediatric patients

The safety profile is similar in children and adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

Barium sulfate is non-toxic and absorbed systemically in negligible amounts.

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: V08BA 01

The active constituent of Maxibar, barium sulfate, is inert and has no pharmacological action. It serves only as a radiopaque substance to opacify the gastro-intestinal tract during X-ray examinations.

5.2 Pharmacokinetic properties

Barium sulfate, is absorbed in small, pharmacologically insignificant amounts, and is not metabolised. As a result, it does not produce any systemic effects. It is passed from the body unchanged.

5.3 Preclinical safety data

No remarks.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

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
Cherry flavour powder

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.

Once opened: Following reconstitution, the suspension should be used immediately and must not be stored.

Discard any unused portion.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Store in the original container.

For storage conditions following reconstitution, please refer to section 6.3.

6.5 Nature and contents of container

High density polyethylene (HDPE) bottle with a polypropylene screw-on lid having a liner of three-ply co-extruded material (a foamed, low density polyethylene core between two solid layers of low density polyethylene). The pack contains 340g of Maxibar.

Boxes of 24 bottles.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

The dose may be varied depending on the patient involved.

Reconstitution information for use of Maxibar is provided below.

Maxibar is intended for oral administration following dispersion in water as directed.

Mixing instructions:

1. Add approximately 65 mL of water to the bottle.
2. Secure lid and invert bottle 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.

7 MARKETING AUTHORISATION HOLDER

Bracco Imaging spa
via Egidio Folli 50
20134 Milan
Italy

8 MARKETING AUTHORISATION NUMBER

PA1826/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 1992

Date of last renewal: 3rd November 2007

10 DATE OF REVISION OF THE TEXT

August 2016