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; andSodium 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 listed in section 6.1.

Gastrointestinal Disorders
Patients with any of the following:
– a known or suspected, perforation t of the gastrointestinal tract
– known or suspected tracheo-esophageal fistula
– gastrointestinal haemorrhage
– gastrointestinal ischaemia

– megacolon or toxic megacolon
– necrotising enterocolitis
– severe 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 after gastrointestinal surgery, including snare polypectomy or 'hot' colonic biopsybecause of the potential for post-surgical or post procedural leakage or the potential for gastrointestinal perforation.

Injury, Poisoning and Procedural Complications
Do not use during and up to four weeks after radiotherapy to the rectum or prostate. 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.

Barium Sulfate should not be administered in its dry form. The powder must be reconstituted, and some of the commercially prepared suspensions require further dilution, prior to administration.

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, gastrointestinal fistulae, 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.

Obstruction / Fluid Overload
Barium Sulfate suspensions, after oral administration, have been reported to cause obstruction of the small bowel (impaction) in pediatric patients with cystic fibrosis.
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.

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.

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.

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.

Hereditary Fructose Intolerance
Maxibar contains sorbitol. The addictive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content in sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not be given this medicinal product.
Sorbitol can cause gastrointestinal discomfort and mild laxative effect

Patients on a Controlled Sodium Diet

This medicinal product contains 259 mg sodium per dose, equivalent to 13% of the WHO recommended maximum daily intake for sodium.

4.5 Interaction with other medicinal products and other forms of interactions

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**	
	Clinical Trials* Rare (≥1/10,000 to <1/1,000)	**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	Abdominal pain Vomiting Nausea	Intestinal ischaemia Gastrointestinal obstruction Gastrointestinal perforation Gastrointestinal ulcer Colitis ulcerative aggravated Gastrointestinal inflammation Abdominal distension

		Abdominal discomfort Constipation Diarrhoea Retching 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 and an aluminium seal. 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 produce 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:

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.

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

April 2019