Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Baricol 1.05 g/ml Rectal Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Barium Sulphate 1.05 g/ml.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Rectal Suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

‘Baricol’ is a radiopaque diagnostic agent for use in air double contrast X-ray visualisation of the lower gastro-intestinal tract.

4.2 Posology and method of administration

‘Baricol’ is intended for rectal (enema) administration. The dosage administered will be dependent upon the patient and the technique involved and will be determined from experience by the radiologist.

Adults: The volume administered will normally be about 600 ml.

Children: The quantity of ‘Baricol’ should be determined, from experience, by the physician and will be dependent on the age and weight of the child.

Elderly: Radiological examinations in the elderly should be carried out with extreme care and the dosage determined by the radiologist.

At the time of the examination the large bowel should be free of any residues that may interfere with the X-ray examination.

4.3 Contraindications

‘Baricol’ should not be used in patients with unclear abdomen with irritated peritoneum and known or suspected perforation; postoperative suture insufficiency, intestinal fistulae with a passage to the mediastinum, pleural cavity or peritoneal cavity; fresh injuries or chemical burns of the oesophageal-gastro-intestinal tract, ischemia of the intestinal wall, necrotising enterocolitis and immediately before surgery of the gastro-intestinal tract.
It should not be used in patients with hypersensitivity to barium sulphate or to any of the excipients.

4.4 Special warnings and precautions for use

The product should be used under medical supervision. ‘Baricol’ as with other barium sulphate enema preparations, should be used cautiously in infants and elderly patients with pre-existing organ injuries (multimorbidity) mainly of the cardiovascular system since the examination including measures for preparation may be stressful to these patients. A careful benefit/risk consideration is required in patients with high-grade stenoses especially those distal to the stomach and in conditions and illnesses with increased risks of perforation such as known gastro-intestinal fistulae and carcinomas, inflammatory intestinal disease, diverticulitis and diverticulosis and amoebiasis. Depending on the location and extent of the intervention ‘Baricol’ should not be used for up to 7 days after an endoscopic excision nor during and up to 4 weeks after concomitant radiotherapy.

To prevent potentially serious adverse reactions penetration of barium sulphate into parenteral areas like tissues, vascular space and body cavities or the respiratory tract must be avoided. Adequate hydration after the procedure should be ensured to prevent severe constipation.

As with any barium sulphate preparation, care should be taken when administering ‘Baricol’ by enema to children, the elderly or the debilitated.

‘Baricol’ contains sodium benzoate, which is a mild irritant to the skin, eyes and mucous membrane and it contains potassium sorbate, which is irritant and can cause dermatitis.

4.5 Interaction with other medicinal products and other forms of interaction

A pharmaceutical or otherwise induced reduction of intestinal peristalsis may lead to an obstruction via thickening of the barium sulphate suspension.

4.6 Pregnancy and lactation

In principle there are no objections against using barium sulphate during pregnancy. Since radiation exposure during pregnancy should be avoided anyway, regardless whether a contrast agent is used or not, the benefit of X-ray examination has to be considered carefully.

Barium sulphate is not absorbed systemically and is, therefore, not contra-indicated during lactation.

4.7 Effects on ability to drive and use machines

‘Baricol’ has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Constipation may occur following a barium sulphate enema (1 in 500,000)**,** rarely impaction, obstruction and appendicitis have occurred. Barium sulphate enemas may exacerbate ulcerative colitis. Rare cases of allergic reactions (urticaria, anaphylactic shock, rashes) have been mentioned in the literature (1 in 250,000).

During a barium procedure, intestinal perforation may rarely occur and may be followed by peritonitis and granuloma. Intravasation and embolisation of barium may also occur rarely.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Contrast Media, Barium Sulphate.

ATC code: ***VO8B***.

Barium sulphate itself has no pharmacological effects. Its use is based on the absorption of X-rays during visualisation of the gastro-intestinal tract.
Pure barium sulphate after enteral application is chemically inert and under physiological conditions practically insoluble and non-toxic. No systemic effect of barium sulphate was revealed by toxicological examinations. No local changes to the mucous membrane of the gastro-intestinal tract were observed.

5.2 Pharmacokinetic properties

Not applicable. Barium sulphate, the active constituent of ‘Baricol’ is not absorbed from the gastro-intestinal tract.

5.3 Preclinical safety data

The toxicological evaluation of barium sulphate did not reveal any systemic effect. Reproduction toxicity, mutagenicity and carcinogenicity have not been investigated which are, however, not to be expected because of the insolubility of the substance.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Simethicone emulsion (including methylcellulose and sorbic acid)
Xanthan gum (E415)
Spray-dried acacia
Sodium carrageenan (E407)
Potassium sorbate (E202)
Sodium benzoate (E211)
Potassium chloride
Vanilla flavoured liquid (including propylene glycol, natural and artificial flavouring, caramel colour and water)
Anhydrous citric acid
Sorbitol (E420)
Sodium citrate dihydrate (E331)
Polyoxyethylene glyceryl mono-oleate
Sodium saccharin
Concentrated hydrochloric acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

Use within 7 days of opening the container.

6.4 Special precautions for storage

Do not freeze.
If the product has been diluted prior to use, then the diluted suspension should be uses immediately and any unused suspension discarded immediately after initial use.

6.5 Nature and contents of container

High density polyethylene bottle with polypropylene screw-on closure containing 600 ml ‘Baricol’.

High density polyethylene bottle with polypropylene screw-on closure containing 1900 ml ‘Baricol’.

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

‘Baricol’ is intended for rectal (enema) administration only. Shake well before using.

‘Baricol’ should be used undiluted to perform double contrast barium enema studies. Should a clinician wish to use a suspension of lower density, ‘Baricol’ may be diluted with water to achieve the desired density required by the radiologist. If the product has been diluted prior to use, then the diluted suspension should be discarded immediately after initial use.

7 MARKETING AUTHORISATION HOLDER

E-Z-EM Nederland b.v.
Planckstraat 69
3316 GS Dordrecht
The Netherlands

8 MARKETING AUTHORISATION NUMBER

PA 1037/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 December 2002

10 DATE OF REVISION OF THE TEXT