

The taste of a right diagnosis in CT

Ready to use flavoured barium for all oral CT examinations



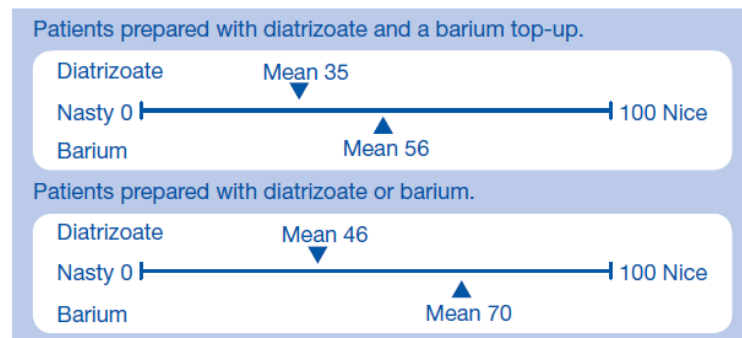
E-Z-CAT™



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Focus on the patient:

- E-Z CAT is well accepted by the patients due to the taste more palatable than that one of ionic iodinate contrast agent.¹



- E-Z-CAT has a good safety profile with a low tendency to provoke nausea and vomiting.^{1,2}

Focus on Diagnosis:

- E-Z-CAT was the first contrast agent specifically designed for bowel marking in Computed Tomography (CT).³
- E-Z-CAT provides good bowel opacification with homogenous density to deliver good quality images with minimal artefacts. The quality of opacification is generally equivalent to that achieved with ionic iodinated agents: some trials have noted a superiority of E-Z-CAT in the caecum /ascending colon and duodenum.⁴

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT E-Z-CAT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituent: Barium Sulphate Ph.Eur. 4.9187% w/v (4.6% w/w)

3. PHARMACEUTICAL FORM Oral suspension.

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS E-Z-CAT is indicated for the opacification of the gastro-intestinal tract prior to computerised axial tomography.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION E-Z-CAT is for oral administration.

Adults and the Elderly: 350 - 450 ml of diluted suspension 30 minutes prior to the scan and the same volume 5 minutes prior to the scan, or, as directed by the physician.

Children: The quantity of 'E-Z-CAT' should be determined, from experience by the physician and will be dependent on the age and weight of the child.

4.3. CONTRA-INDICATIONS E-Z-CAT should not be used in patients where Barium Sulphate is contra-indicated.

4.4. SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE The product should be used under the supervision of a physician. The product contains 15.9 g sorbitol. When taken according to the dosage recommendations, each dose supplies up to 15.9 g of sorbitol.

Unsuitable in hereditary fructose intolerance. Can cause stomach upset and diarrhoea.

This product also contains 50 mg potassium and is harmful to people on low potassium diet. Hyperkalaemia (a high level of potassium in the blood), can cause stomach upset and diarrhoea following oral administration.

This product also contains 206 mg sodium which may be harmful to people on low sodium diets.

4.5. INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION None known.

4.6. PREGNANCY AND LACTATION Barium Sulphate is inert, non-toxic and not absorbed from the gastro-intestinal tract. Radiographic procedures may, however, be harmful to the foetus particularly during the first trimester. E-Z-CAT may be administered during lactation.

4.7. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES None known.

4.8. UNDESIRABLE EFFECTS Occasional nausea has been reported and, less frequently, retching, diarrhoea and constipation.

4.9. OVERDOSE Barium Sulphate is non toxic.

5. PHARMACOLOGICAL PROPERTIES

5.1. PHARMACODYNAMIC PROPERTIES

The active constituent of 'E-Z-CAT', Barium Sulphate, is inert and has no pharmacological action. It serves only as a radiopaque substance to opacify the gastro-intestinal tract during computed axial tomography.

5.2. PHARMACOKINETIC PROPERTIES Barium Sulphate is practically insoluble in water, organic solvents and solutions of acids and alkalis. It is a contrast medium for opacification of the gastro-intestinal tract. It is not absorbed and hence does not produce any systemic effects.

5.3. PRECLINICAL SAFETY DATA No remarks.

6. PHARMACEUTICAL PARTICULARS

6.1. LIST OF EXCIPIENTS Sorbitol (E420), Pectin (E440), Xanthan Gum (E415), Simethicone Emulsion, Potassium Sorbate (E202), Methyl Parahydroxybenzoate (E218), Sodium Saccharin, Liquid Orange Flavour, Sodium Citrate (E331), Polyoxyethylene Glyceryl Mono-oleate, Proprietary Gum (Sodium Carrageenan), Citric Acid, Purified Water.

6.2. INCOMPATIBILITIES None known.

6.3. SHELF-LIFE Three years from the date of manufacture.

6.4. SPECIAL PRECAUTIONS FOR STORAGE Do not freeze.

6.5. NATURE AND CONTENTS OF CONTAINER High density polyethylene bottle with polypropylene screw-on cap with aluminum tamper-evident seal containing 225 ml

6.6. INSTRUCTIONS FOR USE/HANDLING Shake well before use. 'E-Z-CAT' is intended for dilution prior to administration. Pour the contents into a litre container. Add water to give a total volume of 900 ml. Shake well to yield 900 ml of 1.2% w/v Barium Sulphate suspension. Alternatively, 'E-Z-CAT' may be mixed to yield a different density:-

Pour 'E-Z-CAT' contents into mixing container:-

- Add water to 700 ml. Yield a 1.6% w/v suspension.

- Add water to 600 ml. Yield a 1.5% w/v suspension.

- Add water to 500 ml. Yield a 2.2% w/v suspension.

7. MARKETING AUTHORIZATION HOLDER The Marketing Authorisation Holder, Number, and Date of Approval may be different in different Countries. Volumes, presentations, and indications may also differ. Refer to Locally Summary of Product Characteristics. Please contact Bracco Imaging SpA – Via Egidio Folli, 50 20134 Milano-Italy for further information.

8. DATE OF (PARTIAL) REVISION OF THE TEXT October 2009

Literature:

1. Chambers S E, Best J J K. A Comparison of Dilute Barium and Dilute Water Soluble Contrast in Opacification of the Bowel for Abdominal Computed Tomography. *Clinical Radiology* 1984; 35: 463-464.
2. Nyman U, Dinnetz G, Anderson I. E-Z-CAT & BARICAT(tm) An Oral Contrast Medium for use in Computed Tomography of the Abdomen. *Acta Radiologica Diagnosis* 1984; 25: Fasc. 2.
3. EZ-CAT spc
4. Kivisaari L, Korman M. Comparison of Diatrizoate and Barium Sulphate Bowel Markers in Clinical CT. *European Journal Radiology* 1982; 2: 33-34.