

Tailored for the stomach

High-Density Barium Sulphate for Suspension:
Variable barium particle sizes
Low viscosity
Effective anti-foaming and coating agents

SUMMARY OF PRODUCT CHARACTERISTICS

- 1. NAME OF THE MEDICINAL PRODUCT E-Z-HD
- 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituent : Barium Sulphate Ph. Eur. (except sedimentation) 98.45 %w/w

- 3. PHARMACEUTICAL FORM Powder.

For preparation as a suspension following the addition of water as directed.

- 4. CLINICAL PARTICULARS

4.1 Therapeutic Indications E-Z-HD is a high density suspension 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 E-Z-HD is for recommended for oral administration: Adults: The contents of one prefilled bottle (340 g) are dispersed in 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. The dose may be varied depending on the patient involved.

Children: The dosage will be dependent on the age and size of the child. Individual requirements should be determined, from experience, by the radiologist.

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

4.3 Contra-Indications E-Z-HD should not be used in patients with suspected perforation or obstruction of any part of the gastro-intestinal tract, gastric outflow problems or in those other cases where the use of barium sulphate is contra-indicated.

4.4 Special Warnings and Special Precautions for Use This product should be used under medical supervision.

4.5 Interaction with other Medicinal Products and Other Forms of Interaction None known.

4.6 Pregnancy and Lactation Whilst this product itself is not contra-indicated in pregnancy as barium sulphate is not absorbed, it should be noted that radiographic procedures may be harmful to the foetus. Barium sulphate is not absorbed systemically and is, therefore, not contra-indicated during lactation.

4.7 Effects on Ability to Drive and Use Machines As far as is known, barium sulphate has no effects on driving or the ability to use machines.

4.8 Undesirable Effects During or following any barium procedure, complications can occur. These may include intravasation leading to formation of emboli and aspiration into the lungs leading to pneumonitis or granuloma formation. Side-effects include constipation and rarely barium impaction in the colon.

4.9 Overdose Barium sulphate is non-toxic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties Barium sulphate is an X-ray contrast medium. It increases the absorption of X-rays as they pass through the body enabling delineation of the gastro-intestinal tract.

5.2 Pharmacokinetic Properties Barium sulphate is not absorbed or metabolised and hence does not produce any systemic effects. It is passed from the body unchanged.

5.3 Pre-clinical Safety Data Not presented.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients Sorbitol Ph. Eur., Sodium Carageenan, Simeticone USP, Polyoxyethylene Glyceryl Mono-oleate, Ethyl Maltol US FCC*, Sodium Saccharin Ph.Eur., Strawberry Flavour, Cherry Flavour, Sodium Citrate Dihydrate Ph.Eur.

*USFCC = United States Food Chemical Codex.

6.2 Incompatibilities None known.

6.3 Shelf Life

6.3.1 Shelf-life as packaged for sale 'E-Z-HD' has a shelf-life of three years from the date of manufacture.

6.3.2 Shelf-life after reconstitution according to directions 'E-Z-HD' should be used immediately following reconstitution as directed.

6.3.3 Shelf-life after first opening the container No applicable. 'E-Z-HD' is presented in a unit dose which allows for preparation for each patient as required. It is recommended that the reconstituted product is not stored.

6.4 Special Precautions for Storage Store below 25o C in a dry place.

6.5 Nature and Content of Container Unit dose bottle (containing 340 g of 'E-Z-HD') composed of high density polyethylene (HDPE) 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).

6.6 Instructions for Use, Handling and Disposal

- Add 65 ml of water to bottle.
- Secure lid and invert bottle, tapping base to loosen powder.
- Shake well for 10-20 secs. Leave until required.
- Immediately before giving to patient to drink shake again for 10-20 secs.
- Do not store reconstituted product.

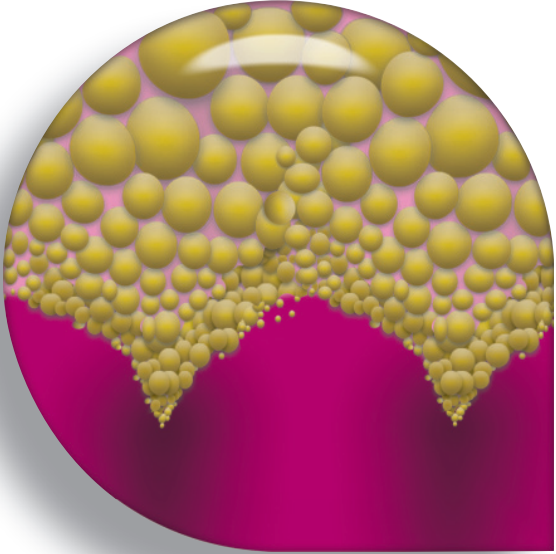
ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION 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

References:

1. Laufer I. Double Contrast Gastrointestinal Radiology with Endoscopic Correlation 1979; 13.
2. Bell JM, Glatthaar et al. A comparison of two high-density barium sulphate preparations for double-contrast barium meals. Clinical Radiology 1984; 35:367-368.
3. Virkkunen P, Retulainen P. Visualization of the area gastricae in double-contrast examination. Gastrointest Radiol 1980; 5:325-329.



E-Z-HD™



E-Z-HD™

250% w/v for Double-Contrast Examination

Improved Mucosal Detail

E-Z-HD has a unique composition of large and small particles to help improve definition and visualization of mucosal detail with less volume.¹

Study Comparing E-Z-HD with Competitor

A study² carried out at the Bristol Royal Infirmary in the United Kingdom compared E-Z-HD to a leading competitor's high-density barium sulphate for suspension. The study involved 93 patients; 46 were given E-Z-HD and 47 received the competitor's product.

E-Z-HD means:

Convenience

E-Z-HD is supplied in unit-dose cups. Simply add 65 mL of water and shake.

Palatable

E-Z-HD has a pleasant, fruit flavour to help enhance patient acceptability.

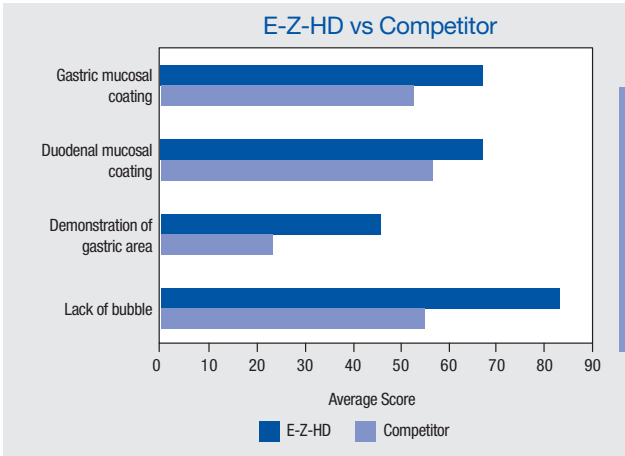
Performance

E-Z-HD is formulated with a unique composition designed to perform more effectively, from general purpose formulations to more recent, "high-density" imitations.

Consistent Quality Imaging

Patients may present with a variety of pH levels in the stomach due to conditions such as smoking, injection of fluids, weather or dehydration. E-Z-HD's proprietary formula is engineered to be resistant to such influences allowing consistent, high quality images from each patient.³

Of the Esophagus, Stomach and Duodenum



The results showed that E-Z-HD provides significantly better coating of the gastric and duodenal mucosa, better demonstration of the gastric area, and is significantly less likely to produce bubbles than the competitor's product ¹

Results: Median ratings for each preparation

	E-Z-HD	Competitor	Significance
Gastric mucosal coating	67	53	p<0.001
Duodenal mucosal coating	67	57	p<0.001
Demonstration of gastric area	46	23	p<0.001
Lack of bubble	83	55	p<0.001

Both products were prepared as recommended by manufacturer. Carbex® was used in all examinations. X-rays were assessed independently by three radiologists who: were unaware of the barium formulation used in the procedure, used a linear analog scale to score the x-rays, and created a median score for each criterion produced.

Feature	Advantage	Benefit
250% w/v	Highest available density barium suspension	Detailed imaging on x-ray
Variable particle size	Barium particles fill crevices in the mucosa	Fine detail visible on x-ray
Low viscosity	Rapid coating and a thin layer	Fast examination and fine detail of mucosa