E-Z-HD™

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
4. CLINICAL PARTICULARS
   4.1 Therapeutic indications: E-Z-HD™ is for oral administration:

   Adults:
   - Add 65 ml of water to bottle.
   - Secure lid and invert bottle, tapping base to loosen powder.
   - Shake for 10-20 seconds. Leave until required.
   - Immediately before giving to patient to drink.
   - Shake again for 10-20 seconds.

   Children:
   - Add 32.5 ml of water to bottle.
   - Secure lid and invert bottle, tapping base to loosen powder.
   - Shake well for 10-20 seconds. Leave until required.
   - Immediately before giving to patient to drink.
   - Shake again for 10-20 seconds.

   Elderly:
   - Add 32.5 ml of water to bottle.
   - Secure lid and invert bottle, tapping base to loosen powder.
   - Shake well for 10-20 seconds. Leave until required.
   - Immediately before giving to patient to drink.
   - Shake again for 10-20 seconds.

5. PHARMACOLOGICAL PROPERTIES
   5.1 Pharmacodynamic Properties: E-Z-HD™ should be used under medical supervision.

   5.2 Pharmacokinetic Properties: E-Z-HD™ should be used under medical supervision.

   5.3 Pre-clinical Safety Data: E-Z-HD™ should be used under medical supervision.

   5.4 Special Warnings and Special Precautions for Use: E-Z-HD™ should be used under medical supervision.

   5.5 Contra-Indications: E-Z-HD™ should be used under medical supervision.

6. PHARMACEUTICAL PARTICULARS
   6.1 List of Excipients: E-Z-HD™ is for oral administration:

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


6.2 Incompatibilities: None known.

6.3 Shelf Life: E-Z-HD™ should be used under medical supervision.

6.4 Special Precautions for Storage: E-Z-HD™ should be used under medical supervision.

6.5 Nature and Content of Container: E-Z-HD™ should be used under medical supervision.

6.6 Instructions for Use, Handling and Disposal: E-Z-HD™ should be used under medical supervision.

7. MARKETING AUTHORISATION HOLDER: Bracco Imaging SpA – Via Egidio Folli, 50 20134 Milano-Italy

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

Tailored for the stomach

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

E-Z-HD™

BARIUM

References:
1. Laufer I. Double Contrast Gastrointestinal Radiology with Endoscopic Correlation 1979; 13
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.

Results: Median ratings for each preparation

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

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

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.²