HAUTE AUTORITÉ DE SANTÉ

HEPATO-GASTRO-ENTEROLOGY
New medicinal product
November 2014

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

IZINOVA (sodium sulfate, magnesium sulfate, potassium sulfate), bowel-cleansing preparation

No clinical added value demonstrated in bowel cleansing by comparison with preparations containing PEG

Main points

- IZINOVA has Marketing Authorisation in adults for bowel cleansing prior to all procedures requiring a clean bowel.
- It has shown its non-inferiority in terms of efficacy in comparison with MOVIPREP taken in a single- or split-dose regimen, and its superiority in comparison with PICOREP taken in a split-dose regimen.

Therapeutic use

Three types of products are used for cleansing the bowel in preparation for a diagnostic or therapeutic procedure: solutions containing polyethylene glycol (PEG) based on a mechanical mode of action, products containing sodium phosphate based on an osmotic mode of action and requiring patients to be rehydrated, and solutions containing sodium picosulfate and magnesium citrate.

Role of the medicinal product in the therapeutic strategy

The role of IZINOVA is the same as that of other products prescribed for bowel cleansing prior to endoscopic or radiological examination in adult subjects, in the absence of severe renal failure or congestive heart failure and severe fluid and electrolyte imbalance.

Clinical data

- Two randomised, single-blind, controlled, phase III clinical studies showed the non-inferiority of IZINOVA by comparison with MOVIPREP with bowel cleansing success rates of 82.4% versus 80.3% in a single-dosing regimen, and 97.2% versus 95.6% in a split-dose regimen.
- A phase IV study using a split-dose administration regimen showed the superiority of IZINOVA by comparison with PICOPREP with a bowel cleansing success rate of 94.6% versus 85.7%, respectively. There were no studies comparing IZINOVA with products containing PEG.
- The main adverse events were gastrointestinal in nature, with abdominal distension and pain, and nausea and vomiting, the latter being more common when not following a split-dose regimen.

Benefit of the medicinal product

- The actual benefit* of IZINOVA is substantial.
- IZINOVA does not provide a clinical added value** (CAV V, none) in bowel cleansing by comparison with the reference bowel cleansing solutions containing PEG.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 22 October 2014 (CT-13127) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement by the National Health Insurance.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.