

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

CETORNAN 5 g (ornithine), treatment of liver disease

Insufficient actual benefit as an adjuvant to nutrition in elderly undernourished subjects

Main points

- ▶ CETORNAN 5 g has Marketing Authorisation as an adjuvant to nutrition in elderly undernourished subjects
- ▶ In the absence, because of its ill-defined role in the therapeutic strategy, of clinical data that establish beyond doubt the efficacy of ornithine in the indication given in the Marketing Authorisation and in the opinion of experts, the actual benefit of CETORNAN 5 g and its generic equivalents is insufficient for reimbursement by National Health Insurance.

Therapeutic use

- The nutritional treatment strategy is based on the nutritional status of the patient and the spontaneous level of food energy and protein intake.
- **Role of the medicinal product in the therapeutic strategy**
In view of:
 - the absence of clinical data that demonstrate the efficacy of CETORNAN 5 g,
 - the non-medicinal alternatives based on an enriched diet,
 - the absence of guidelines recommending the prescription of ornithine in elderly undernourished subjects, CETORNAN 5 g does not have a role in the treatment of elderly undernourished subjects.

Clinical data

- There are no studies meeting current methodological standards that demonstrate the efficacy of this proprietary medicinal product in the indications given in the Marketing Authorisation, even though a study of this type could have been conducted.

Benefit of the medicinal product

- The actual benefit* of CETORNAN 5 g is insufficient to justify reimbursement by National Health Insurance.
- Does not recommend continued 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 04 November 2015 (CT-14039) and is available at www.has-sante.fr

ⁱ * 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 for hospital use.