HAUTE AUTORITÉ DE SANTÉ

CARDIOLOGY
Update
January 2019

TRANSPARENCY COMMITTEE OPINION SUMMARY

NAFTILUX (naftidrofuryl), peripheral vasodilator

Insufficient clinical benefit to justify reimbursement in the symptomatic treatment of intermittent claudication in peripheral arterial disease due to the absence of role in the therapeutic strategy

Main points

- NAFTILUX has an MA for the symptomatic treatment of intermittent claudication in peripheral arterial disease (stage 2).
- Naftidrofuryl has demonstrated a modest effect versus placebo on improvement of walking distance, the clinical relevance of which is debatable today, particularly in view of the occurrence of cases of serious liver damage.
- It has no role in the therapeutic strategy for the management of intermittent claudication in peripheral arterial disease (PAD).

Therapeutic strategy

- The management of intermittent claudication in PAD has changed since the last evaluation of this medicinal product. European recommendations now cite peripheral vasodilators (including naftidrofuryl) as marginal treatments.
- **Role of the medicinal product in the therapeutic strategy**

  In view of:
  - the modest efficacy of naftidrofuryl compared to placebo, demonstrated solely on a symptomatic endpoint - pain-free walking distance - in several old clinical trials that do not correspond to current treatment conditions, and its low clinical relevance,
  - the safety profile of this medicinal product, with the occurrence of cases of serious liver damage, such as acute cytolytic hepatitis,

  naftidrofuryl no longer has a role in the therapeutic strategy for the management of intermittent claudication in peripheral arterial disease.

Clinical data

- The efficacy of naftidrofuryl was demonstrated versus placebo in several clinical trials and meta-analyses, with an effect size judged modest at best and in old clinical trials that do not correspond to current treatment conditions.
- The addition of cases of “serious liver damage, such as acute cytolytic hepatitis”, without the SPC mentioning the frequency associated with this adverse reaction.

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Benefit of the medicinal product

- The actual clinical benefit* of NAFTILUX is insufficient.
- Not approved for continuing non-hospital pharmacy reimbursement or for hospital treatment.

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This document was drafted on the basis of the Transparency Committee opinion dated 23 January 2019 (CT-16271) available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a 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 ACB, which may be high, moderate, low, or insufficient for the medicinal product to be covered by public funding.

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