SUMMARY

nifedipine/lidocaine hydrochloride
NIFEXINE, 0.3 g/1.50 g,

rectal cream

First assessment

Original French opinion adopted by the Transparency Committee on 1 February 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement of NIFEXINE (nifedipine/lidocaine hydrochloride) in adults in the “treatment of pain associated with chronic anal fissures following the failure of the usual treatments for acute symptoms of anal fissure”.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

The clinical data available do not enable the role of NIFEXINE (nifedipine/lidocaine hydrochloride) to be defined in comparison with RECTOGESIC (glyceryl trinitrate) cream to relieve the pain associated with chronic anal fissures following the failure of the usual treatments for acute symptoms of anal fissure.

Although surgery is more effective, medicinal products do not expose patients to its possible complications (risk of infection and continence problems in particular).

In sum, NIFEXINE (nifedipine/lidocaine hydrochloride) is a new treatment option.

Transparency Committee's conclusions

Clinical Benefit

- Seriousness of the disease: chronic anal fissure is a condition that is not usually serious, but which leads to intense and sometimes disabling pain and an impaired quality of life.
- The proprietary medicinal product NIFEXINE (nifedipine/lidocaine hydrochloride) is a symptomatic medicinal product.
- The efficacy/adverse effects ratio of NIFEXINE (nifedipine/lidocaine hydrochloride) is low, with an efficacy that has been inadequately established for pain and the risk of recurrences.
- There are few alternatives apart from surgery.
- This is a second-line treatment following the failure of the usual treatments for acute symptoms of anal fissure.

- **Public health benefit**

Considering:

- the seriousness of the disease, chronic anal fissure being a condition that is not usually serious, but which leads to intense and sometimes disabling pain and an impaired quality of life.
- the partially met medical need;
- the lack of any demonstrated additional impact on morbidity (reduction in pain, improvement of healing) in the absence of comparative data versus RECTOGESIC cream or a placebo;
- the lack of an expected additional impact on quality of life, the organisation of care and the patient's care and/or life pathway;

NIFEXINE (nifedipine/lidocaine hydrochloride) is unlikely to have an additional impact on public health.

Given all these elements, the Committee deems that the clinical benefit (CB) of NIFEXINE (nifedipine/lidocaine hydrochloride) is low in the MA indication.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication and at the marketing authorisation dosages.

Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 15%

Clinical Added Value

Considering:

- the low level of evidence of clinical efficacy: study with an acceptable methodology (randomised controlled trial), but single-centre (55 patients per group) with a questionable choice of comparator (combination of 1% hydrocortisone acetate and 1.5% lidocaine cream not recommended in routine practice and off-label). In addition, the benefit of lidocaine has not been demonstrated in this indication (see Cochrane review);
- the effect size on relevant healing but with an effect on pain relief that is inadequately established and without any clearly determined effect on recurrences,
- the absence of quality of life data;

the Committee deems that NIFEXINE 0.3 g/1.50 g (nifedipine/lidocaine hydrochloride) rectal cream provides no clinical added value (CAV V) in adults to relieve the pain associated with chronic anal fissures following the failure of the usual treatments for acute symptoms of anal fissure.