

SUMMARY

etilefrine

EFFORTIL**5-mg tablets/ oral solution in drops at a concentration of
0.5 mg/drop**

First listing

Adopted by the Transparency Committee on 25 September 2024

Summary of opinion

Unfavourable opinion for reimbursement in “the treatment of low-flow priapism in adults, particularly in sickle cell disease, and in the secondary prevention of low-flow priapism in adults and children over 2 years of age (solution in drops) or 6 years of age (tablets), particularly in sickle cell disease.”

Transparency Committee’s conclusions**Clinical Benefit**

- ➔ In the event of low-flow priapism, erections are generally painful. Recurrences, sometimes numerous, impair quality of life and erectile function. When priapism persists for more than 3 to 4 hours, it induces a risk of corpus cavernosum fibrosis and impairment of erectile function.
- ➔ This is a symptomatic and preventive medicinal product.
- ➔ The efficacy/adverse effects ratio of oral etilefrine has not been established in the treatment of low-flow priapism, and is inadequately established in adults and children in secondary prevention, with, in addition, an uncertain dosage.
- ➔ Oral etilefrine has no role in the MA indications, in view of the therapies available.

→ Public health benefit

Considering:

- the seriousness of low-flow priapism and its rarity in adults and children,
- the inadequately met medical need,
- the inadequately established response to the identified need, given:
 - the very low level of evidence of the clinical benefit of oral etilefrine in adults and children to prevent recurrences of priapism,
 - the lack of an established additional impact on morbidity and mortality and on quality of life, on the organisation of care and the patient's care and life pathway,

EFFORTIL (etilefrine) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of oral EFFORTIL (etilefrine) is insufficient in the MA indications to justify public funding in view of the available alternatives.

The Committee issues an unfavourable opinion for inclusion of oral EFFORTIL (etilefrine) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indications and at the MA dosages.

EFFORTIL 25 September 2024

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