

SUMMARY

verapamil hydrochloride

**ISOPTINE 40 mg and
120 mg,
ISOPTINE LP 240 mg,****coated tablets, hard capsules, slow-release scored film-coated tablets****New indication(s)****Adopted by the Transparency Committee on 10 May 2023****The legally binding text is the original French opinion version****Key points**

Favourable opinion for reimbursement in the MA indication.

Role in the care pathway?

Verapamil is a first-line treatment in the prevention of cluster headaches.

Transparency Committee's conclusions

Clinical Benefit

- Cluster headaches are a severe and incapacitating condition impairing patients' quality of life.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is high in the prevention of cluster headaches.
- This is a first-line treatment in the prevention of cluster headaches.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the inadequately met medical need,
- the partial response to the identified need with:
 - an additional impact on morbidity of verapamil 360 mg compared to placebo in terms of reduction of the frequency of episodic cluster headache attacks with, nonetheless, a low level of evidence.
 - an impact on quality of life suggested by the impact on attacks,
 - the lack of evidence of an additional impact on the organisation of care,

the proprietary medicinal products ISOPTINE and ISOPTINE LP (verapamil) are unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of the proprietary medicinal products ISOPTINE and ISOPTINE LP (verapamil) is substantial in the indication extension to the prophylactic treatment of cluster headaches, and at the MA dosages.

The Committee issues a favourable opinion for inclusion of ISOPTINE and ISOPTINE LP (verapamil) in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication extension to the prophylactic treatment of cluster headaches, and at the MA dosages.

- **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%**

Clinical Added Value

Considering:

- efficacy data from the literature having reported a superiority of verapamil 360 mg compared to placebo on reduction of the frequency of episodic cluster headache attacks with, nonetheless, a low level of evidence (study conducted on 30 patients, without calculation of the number of subjects required, duration limited to two weeks, questions with respect to transposability),
- the known safety profile of verapamil and the specific cardiovascular warnings associated with this indication extension,
- and despite the inadequately met medical need in this severe condition,

the Committee considers that the proprietary medicinal products ISOPTINE and ISOPTINE LP (verapamil) provide no clinical added value (CAV V) in the current care pathway.