SUMMARY

sumatriptan 85 mg/naproxen 500 mg

NOMANESIT 85 mg/500 mg

film-coated tablet

Inclusion on list

Adopted by the Transparency Committee on 18 December 2024

Summary of opinion

Favourable opinion for reimbursement only for the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences.

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee's conclusions

Clinical Benefit

- Migraine is a chronic, disabling condition that, due to the frequency and severity of attacks, can lead to severe impairment of quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is:
  - high in the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences, as long as the contraindications and special warnings and precautions for use are complied with.
  - not established in the other situations of the MA.
- It is a second-line option in view of the therapies available for the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences. However, NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) has no role in other MA situations.

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of response to the identified need given:
  - the lack of evidence of an additional impact on morbidity in the treatment of migraine attacks,
  - the lack of evidence of an additional impact on quality of life,
  - the lack of evidence of an additional impact on the organisation of care,

NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) is unlikely to have an additional impact on public health compared to the separate use of the individual components of the combination.

Considering all of these elements, the Committee deems that the clinical benefit of NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) is:

- **substantial only for the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences,**
- **insufficient to justify public funding in view of the available alternatives in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only for the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences,**
- **an unfavourable opinion for inclusion of NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the other MA situations.**

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- evidence of the superiority of a single dose of the NOMANESIT combination (sumatriptan 85 mg/naproxen sodium 500 mg) versus placebo and versus active substances as monotherapy in only one of the two studies in patients with a mean monthly frequency of 2 to 6 moderate to severe migraine attacks in the past three months (without specification of the mean number of monthly attacks),
- the percentage of patients having previously received treatment with oral sumatriptan (31%) during the studies concerned, without specification of failure or otherwise of this previous treatment,
- recommendations that have been in place for several years to combine a triptan and an NSAID as part of a strategy to optimise treatment of attacks when triptan is ineffective,
- the safety profile reported in the short term for this fixed-dose combination (maximum of 12 months), predominantly with a single dose (70% of patients versus 30% having received two consecutive doses) having been similar to the safety profile established for the respective active substances as monotherapy,

the Committee deems that NOMANESIT (sumatriptan 85 mg/naproxen sodium 500 mg) provides no clinical added value (CAV V) in the therapeutic strategy for acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a triptan alone is insufficient and/or in the event of intense recurrences.

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