HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
2 JUNE 2021

The legally binding text is the original French opinion version

perampanel
FYCOMPA, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg film-coated tablets
FYCOMPA 0,5 mg/ml oral suspension

New indications

Key points

Favourable opinion for reimbursement in the treatment of partial-onset seizures (POS) with or without secondarily generalised seizures in patients from 4 years to 11 years of age and in the treatment of primary generalised tonic-clonic (PGTC) seizures in patients from 7 to 11 years of age with idiopathic generalised epilepsy (IGE), in combination with another anti-epileptic treatment.

What therapeutic improvement?

No clinical added value in the therapeutic strategy for the treatment of partial-onset seizures and primary generalised tonic-clonic seizures in children.

Role in the care pathway?

The objective of medicinal treatment is the absence of seizures combined with good tolerability of treatment, where possible. Where this is not possible, medicinal treatment aims to reduce the number of seizures, with the best possible quality of life. The therapeutic strategy should be tailored individually, in liaison with patients and/or their families and/or legal representatives, based on the patient's characteristics (sex, age, etc.), seizure type, syndrome diagnosis, existing medicinal products and treatments, comorbidities and lifestyle. Epilepsy does not systematically require the prescription of a long-term treatment.

Anti-epileptic monotherapy should be used as first-line treatment. When the first-line treatment is not sufficiently effective at the maximum dose or is poorly tolerated, monotherapy using another drug (which may be a first or second-line alternative) should be initiated. The anti-epileptic drug replacement period should be carefully monitored. In the majority of cases, it is recommended to use an anti-epileptic dual therapy when two successive monotherapies, appropriate to the diagnosis of the seizures or syndrome and at optimal doses, have not enabled complete control of seizures.

Role of the medicinal product in the care pathway

FYCOMPA (perampanel) is an additional treatment option in the treatment of partial-onset seizures in patients from 4 years to 11 years of age and in the treatment of primary generalised tonic-clonic seizures in patients from 7 to 11 years of age with idiopathic generalised epilepsy.

The potential benefit of treatment with perampanel should be assessed taking into consideration the product's tolerability and the lack of data relative to the effects of the product on other generalised seizures, such as absence and myoclonic seizures, in particular.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

Partial-onset seizures with or without secondarily generalised seizures in patients from 4 years to 11 years of age

- Repeated epileptic seizures can have direct consequences, such as serious injury, can result in psychological disturbances in the medium to long term and a marked deterioration in quality of life, and can have a detrimental impact on the school and socioprofessional integration of patients. In children and adolescents, epilepsy and its treatment can have a marked impact on the various cognitive, behavioural and social milestones and can lead to sometimes severe neuropsychological and neurodevelopmental problems.
- The proprietary medicinal product FYCOMPA (perampanel) is a symptomatic and/or preventive medicinal product for partial-onset seizures with or without secondarily generalised seizures
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives in the indication.
- FYCOMPA (perampanel) is indicated in partial-onset seizures, in combination with another anti-epileptic treatment.

Public health impact

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified medical need due to non-demonstration of an impact on morbidity and mortality or quality of life in view of the absence of controlled efficacy data,
- the lack of elements capable of supporting a potential impact on the care and/or life pathway of patients, and on the organisation of care,

FYCOMPA (perampanel) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of FYCOMPA (perampanel) is substantial in the treatment of partial-onset seizures with or without secondarily generalised seizures, in combination with another anti-epileptic treatment, in patients from 4 years to 11 years of age.

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 treatment of partial-onset seizures with or without secondarily generalised seizures, in combination with another anti-epileptic treatment, in patients from 4 years to 11 years of age and at the MA dosages.

Primary generalised tonic-clonic seizures in patients from 7 to 11 years of age with idiopathic generalised epilepsy

- Repeated epileptic seizures can have direct consequences, such as serious injury, can result in psychological disturbances in the medium to long term and a marked deterioration in quality of life, and can have a detrimental impact on the school and socioprofessional integration of patients. In children and adolescents, epilepsy and its treatment can have a marked impact on the various cognitive, behavioural and social milestones and can lead to sometimes severe neuropsychological and neurodevelopmental problems.
- FYCOMPA (perampanel) is a symptomatic and/or preventive medicinal product for primary generalised tonic-clonic seizures.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives in the indication.
- FYCOMPA (perampanel) is indicated in primary generalised tonic-clonic seizures, in combination with another anti-epileptic treatment.

Public health impact

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified medical need due to non-demonstration of an impact on morbidity and mortality or quality of life in view of the absence of controlled efficacy data,
- the lack of elements capable of supporting a potential impact on the care and/or life pathway of patients, and on the organisation of care,

FYCOMPA (perampanel) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of FYCOMPA (perampanel) is substantial in the treatment of primary generalised tonic-clonic seizures, in combination with another anti-epileptic treatment, in patients from 7 years to 11 years of age with idiopathic generalised epilepsy.

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 treatment of primary generalised tonic-clonic seizures, in combination with another anti-epileptic treatment, in patients from 7 years to 11 years of age with idiopathic generalised epilepsy and at the MA dosages.

- **Recommended reimbursement rate: 65%**

Clinical Added Value

Considering:

- **the descriptive efficacy data for perampanel relative to the frequency of partial-onset seizures and primary generalised tonic-clonic seizures in patients treated with one to three anti-epileptic drugs,**

but in view of:

- **the partially met medical need,**
- **the absence of controlled data versus placebo and/or an active comparator,**
- **the lack of data in other generalised seizures, such as absence and myoclonic seizures,**

the Committee considers that FYCOMPA (perampanel) provides no clinical added value (CAV V) in the therapeutic strategy for the treatment of partial-onset seizures and primary generalised tonic-clonic seizures in children.