

SUMMARY

perindopril/indapamide/amlodipine

TRIPLIXAM 5 mg/1.25 mg/5 mg, 5 mg/1.25 mg/10 mg, 10 mg/2.5 mg/5 mg and 10 mg/2.5 mg/10 mg

film-coated tablet

New listing request

Adopted by the Transparency Committee on 9 October 2024

Summary of opinion

Favourable opinion for reimbursement as substitution therapy for treatment of essential hypertension, in patients already controlled with perindopril/indapamide fixed-dose combination and amlodipine, taken simultaneously at the same dose level.

Transparency Committee's conclusions**Clinical Benefit**

- ➔ Essential hypertension can be life-threatening due to its complications.
- ➔ This is a preventive medicinal product.
- ➔ The efficacy/adverse effects ratio of perindopril, indapamide and amlodipine taken separately, assessed on the basis of blood pressure values, is high. As substitution therapy, no studies have compared the efficacy, adverse effects and/or quality of life between a fixed-dose triple therapy and a free triple therapy taken separately at the same dose levels. In addition, it has not been demonstrated that the fixed-dose combination of these three antihypertensive drugs has an impact on the reduction of morbidity and mortality. Consequently, the efficacy/adverse effects ratio of TRIPLIXAM (perindopril/indapamide/amlodipine) cannot be determined.
- ➔ This is a last-line treatment for essential hypertension, as substitution therapy, in patients whose blood pressure is already adequately controlled and stabilised with a free combination of perindopril, indapamide and amlodipine, taken concomitantly at the same dosages.

→ Public health benefit

Considering:

- the seriousness of the disease and its high prevalence;
- the partially met medical need;
- the lack of response to the identified need considering:
 - the lack of response to the medical need, with no evidence of a benefit of treatment with this fixed-dose combination compared to free combination of these three active substances,
 - the lack of evidence of an impact on quality of life and on the organisation of care;

TRIPLIXAM (perindopril/indapamide/amlodipine) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of TRIPLIXAM (perindopril/indapamide/amlodipine) film-coated tablet, at the 5 mg/1.25 mg/5 mg, 5 mg/1.25 mg/10 mg, 10 mg/2.5 mg/5 mg and 10 mg/2.5 mg/10 mg strengths, is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of TRIPLIXAM (perindopril/indapamide/amlodipine) film-coated tablet, at the 5 mg/1.25 mg/5 mg, 5 mg/1.25 mg/10 mg, 10 mg/2.5 mg/5 mg and 10 mg/2.5 mg/10 mg strengths, in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

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

Clinical Added Value

Considering:

- expert opinions highlighting the benefit of fixed-dose triple antihypertensive drug combinations, supported by international and European guidelines specifying that these “single pill combinations” should be favoured for dual and triple therapies because they promote patient adherence and compliance with their antihypertensive treatment;
- observational data based on Italian medico-administrative databases reporting a better level of treatment compliance in patients on fixed-dose perindopril/indapamide/amlodipine antihypertensive triple therapy compared to a fixed-dose dual therapy combined with a free component or a free triple combination;
- the absence of any new identified safety signals since the last assessments and safety data in line with the already known safety profiles of the three active substances of the medicinal product;

but in view of:

- the limited clinical interpretation of the compliance data supplied in view of the low level of evidence of the observational studies;
- the absence of clinical data enabling the efficacy of the TRIPLIXAM (perindopril/indapamide/amlodipine) fixed-dose combination to be assessed in the management of patients whose blood pressure is stabilised by the components of this combination;

the Committee deems that TRIPLIXAM (perindopril/indapamide/amlodipine) provides no clinical added value (CAV V) compared to the free combination of perindopril, indapamide and amlodipine taken concomitantly at the same dosage.