

SUMMARY

paliperidone (palmitate)

**TREVICTA 175 mg, 263 mg,
350 mg and 525 mg,****prolonged release suspension for injection****Modification of conditions for inclusion****Original French opinion adopted by the Transparency Committee on
21 June 2023****The legally binding text is the original French opinion version****Transparency Committee's conclusions****Clinical Benefit**

- ➔ The essential characteristics of schizophrenia are the presence of a set of signs and symptoms termed “positive” (delusions, hallucinations, disorganised speech, severely disorganised or catatonic behaviour) or “negative” (blunted emotions, alogia, loss of drive), associated with significant dysfunction in socialisation and activities. The course of schizophrenia is variable; some patients present exacerbations and remissions, while others remain chronically affected. Some patients appear to have a relatively stable course, while others show a progressive worsening of the condition associated with severe disability.
- ➔ This is a symptomatic medicinal product.
- ➔ The efficacy/adverse effects ratio remains high.
- ➔ TREVICTA (3-monthly paliperidone palmitate) is an alternative to monthly injections of paliperidone palmitate (XEPLION) in patients requiring no dose adjustment, provided that spacing out the injections does not adversely affect the patient's medical follow-up, particularly at the time of treatment initiation; the therapeutic strategy for these patients is not solely based on optimising the antipsychotic treatment, but also includes psychosocial rehabilitation interventions and treatment of any comorbidities (psychiatric and somatic).

➔ Public health benefit

Considering the absence of robust demonstration of the benefit of TREVICTA (3-monthly paliperidone palmitate) on public health endpoints (no improvement in quality of life or safety and no reduction in the number of hospitalisations required for follow-up), TREVICTA (3-monthly paliperidone palmitate) is

unlikely to have an additional impact on public health in the current management in patients with schizophrenia who are clinically stable on 1-monthly paliperidone palmitate injectable product.

Considering all these elements, the Committee deems that the clinical benefit of TREVICTA (3-monthly paliperidone palmitate) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of TREVICTA (3-monthly paliperidone palmitate) in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication.

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

Clinical Added Value

Considering:

- initial data having demonstrated the non-inferiority of the efficacy of 3-monthly injections of paliperidone palmitate compared to monthly injections,
- new data that still do not demonstrate any improvement in safety and quality of life compared to monthly injections,

the Committee considers that TREVICTA (3-monthly paliperidone palmitate) provides no clinical added value (CAV V) compared to monthly injections of paliperidone palmitate (XEPLION).