HAUTE AUTORITÉ DE SANTÉ

PSYCHIATRY
New medicinal product
July 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

TREVICTA (paliperidone), antipsychotic

No clinical benefit demonstrated for a 3-monthly injection when compared with monthly injections of paliperidone in the maintenance treatment of schizophrenia.

Main points

- TREVICTA, a 3-monthly injection, has Marketing Authorisation in the maintenance treatment of schizophrenia in adult patients who are clinically stable on monthly paliperidone palmitate injections.
- The non-inferiority of 3-monthly injections of paliperidone palmitate compared with monthly injections has been demonstrated, without improvement in safety or quality of life.
- TREVICTA is to be used only after the patient has been adequately treated with 1-monthly paliperidone palmitate injections, preferably for four months or more, in situations where spacing of the injections would not be detrimental to the patient's regular monitoring, which is at least monthly and which is not limited to the single administration of the medicinal product

Therapeutic use

- Antipsychotics are the conventional pharmacological treatment for schizophrenia, especially second-generation antipsychotics, which have fewer adverse effects than first-generation antipsychotics, and are recommended as first-line antipsychotics.
- During the maintenance phase, the choice is made between the effective neuroleptic taken daily by mouth or the introduction of the same molecule in a long-acting form via injection.
- Long-acting injectable antipsychotics are a therapeutic option when the patient expresses a preference for this type of treatment and/or when there are difficulties maintaining adherence. Their prescription can be considered in a context of therapeutic alliance in a stabilised patient.

Role of the proprietary medicinal product in the therapeutic strategy

TREVICTA is an alternative to 1-monthly injections of paliperidone palmitate (XEPLION) in situations where spacing of the injections would not be detrimental to the patient's regular monitoring, which is at least monthly, and which is not limited to the single administration of the medicinal product (namely psychotherapeutic monitoring, psychoeducation, social rehabilitation).

Clinical data

- A placebo-controlled study showed a longer relapse time in the PP3M (3-monthly paliperidone injection) group compared to the placebo group (HR = 3.5; 95% CI [1.7;6.9]; p<0.001) in 305 patients (out of 506 patients included), who had followed a 17-week PP1M (1-monthly paliperidone injection) initiation/stabilisation phase, then a 12-week PP3M treatment phase.
- A study demonstrated the non-inferiority of treatment with PP3M versus PP1M after 48 weeks of treatment, in terms of percentages of relapse (8 and 9%, respectively), in 995 patients (out of 1,429 patients included), and who had followed a 17-week PP1M initiation/stabilisation phase.
- The most commonly reported adverse events on PP3M versus placebo were headache, weight gain, rhinopharyngitis and hyperprolactinaemia (incidence lower than 9% in the PP3M group). Extrapyramidal symptoms were reported: akathisia (4%), Parkinsonism (4%) and tremor (1%).

Special prescribing conditions

- Initial prescription restricted to psychiatry specialists.
- Unrestricted renewal.

Benefit of the medicinal product

- The actual clinical benefit* of TREVICTA is substantial.
- TREVICTA does not provide clinical added value** (CAV V) by comparison with 1-monthly injections of paliperidone palmitate (XEPLION).
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 05 October 2016 (CT-15341) available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV (equivalent of “no CAV”) means “no clinical added value”.