OPINION ON MEDICINAL PRODUCTS

risperidone

OKEDI 75 mg and 100 mg,

powder and solvent for sustained-release injectable suspension

Availability of hybrid

Adopted by the Transparency Committee on 7 December 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Approval of reimbursement for the treatment of schizophrenia in adults whose tolerance and efficacy have been established with oral risperidone.

Therapeutic improvement?

No therapeutic improvement with respect to the conventional proprietary medicinal product RISPERDAL 4 mg (risperidone) film-coated tablet.

Role in therapeutic strategy?

Antipsychotics are the conventional pharmacological treatment for schizophrenia. They are used for acute phase treatment and as maintenance treatment to prevent relapses.

The choice of antipsychotic accounts for the response to treatments previously received, the safety profile of the antipsychotics and the patient's individual susceptibility to adverse effects. Second-generation antipsychotics are recommended as a first-line approach as their safety is superior to that of first-generation antipsychotics. Antipsychotic monotherapy must be preferred.

A multidimensional approach is required for schizophrenia patients. Drug treatments must be associated with individual or group psychotherapy, institutional or family care and social interventions.

Prescribing a long-acting injectable form may be envisaged where the patient expresses a preference for this type of treatment and/or where compliance problems are observed in patients sufficiently stabilised by oral treatment during the initial treatment phase.

Role of OKEDI (risperidone) in the therapeutic strategy:

The proprietary medicinal products OKEDI (risperidone LP) powder and solvent for sustained-release injectable suspension provide a therapeutic alternative for the treatment of schizophrenia in adults whose tolerance and efficacy have been established with oral risperidone.

Committee's conclusions

Actual Clinical Benefit

- Schizophrenia is a severe disease considering the impairment caused, the age of onset (late adolescence, young adulthood) and its impact on personal, social, family and work life. Outcomes are frequently chronic, due to residual symptoms or relapses, commonly observed in the disease. It is frequently associated with many psychiatric and somatic comorbidities.
- OKEDI (risperidone) 75 mg and 100 mg, powder and solvent for sustained-release injectable suspension is a preventive treatment of long-term schizophrenia recurrences.
- The efficacy/adverse effect ratio of OKEDI (risperidone) is significant for the treatment of schizophrenia in adult patients whose tolerance and efficacy have been established with oral risperidone.
- Alternative medications are available.
- The proprietary medicinal products OKEDI (risperidone LP) powder and solvent for sustained-release injectable suspension provide a therapeutic alternative for the treatment of schizophrenia in adults whose tolerance and efficacy have been established with oral risperidone.

Public health benefit

Considering:

- the severity and high prevalence of schizophrenia.
- the partially met medical need,
- the lack of partial response to the identified need with:
  - the lack of evidence of an additional impact on morbidity-mortality;
  - the lack of evidence of an additional impact on quality of life in terms of compliance in view of its administration schedule (monthly intramuscular injection),
  - the lack of evidence of an additional impact on delivery of care,

OKEDI (risperidone) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of OKEDI (risperidone) is significant in the indication and at the dosages of the marketing authorisation.

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the indication and at the dosages of the marketing authorisation.

Clinical Added Value

Considering:

- **the efficacy data solely based on a study conducted versus placebo for the treatment of acute schizophrenia relapse, moreover with a number of limitations raised (selected study population, different risperidone titration dosage for treatment-naive patients from that validated by the SPC, high attrition rates, etc.),**
- **the lack of efficacy data versus active comparator making it possible to place the medicinal product in the therapeutic strategy, in a context where the therapeutic alternatives in sustained-release form which could be administered to patients whose tolerance and efficacy were established with oral risperidone (*i.e.,* bimonthly injection of risperidone LP or paliperidone LP) demonstrating their non-inferiority versus active comparator,**

but also considering

- **the bioequivalence established with the conventional proprietary medicinal product RISPERDAL 4 mg (risperidone) film-coated tablet,**
- **the known safety profile of risperidone,**
- **the benefit of having dosage forms enabling a different administration schedule,**

the Committee deems that OKEDI (risperidone) provides no clinical added value (CAV V) in relation to the conventional proprietary medicinal product RISPERDAL 4 mg (risperidone) film-coated tablet,