Pharmacotherapeutic report on retigabine (Trobalt®) for the 'adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy'

Medicine. Retigabine, tablet 50 mg, 100 mg, 200 mg, 300 mg.

Summary of the therapeutic value

Intended effects. No direct comparative studies have been carried out in which retigabine was compared with other antiepileptic drugs for the adjunctive treatment of partial epilepsy. In shortterm studies of partial epilepsy, retigabine was statistically significantly more effective than placebo in reducing the frequency of seizures when given in doses of 600 mg, 900 mg and 1200 mg/day in adjunctive treatment with 1-3 other antiepileptic drugs. The evidence for 600 and 900 mg/day is less consistent, as the difference in comparison with placebo was not statistically significant in all studies. When given as adjunctive treatment, retigabine was in indirect comparison not more effective than other antiepileptic drugs that are used as adjuvant (gabapentin, lacosamide, levetiracetam, oxcarbazepine, pregabalin, topiramate, zonisamide). **Unintended effects.** The side effects profile of retigabine differs from that of other antiepileptic drugs and is characterised by many central nervous system (CNS) adverse events, specifically confusion, abnormal thoughts, speech impediment, hallucinations and psychoses and it also hampers urination. Most side effects are dose-dependent. The relevance of the serious side effects, psychosis, hallucinations, severe urine retention, is as yet unclear. Retigabine has a new working mechanism that can lead to cardiac toxicity and other as yet unknown side effects. There are too few data to be able to determine whether retigabine has advantages or disadvantages with respect to tolerance and its side effects profile in comparison with one of the following antiepileptic drugs that are used as adjunctive treatment: gabapentin, lacosamide, levetiracetam, oxcarbazepine, pregabalin, topiramate. With regard to side effects, retigabine is regarded as one of the least safe and least well-tolerated antiepileptic drugs, with a relatively large number of CNS adverse effects on. As far as the CNS adverse effects are concerned, the side effects profile shows most similarity to that of topiramate.

Experience. Experience with retigabine is limited and less than with the other antiepileptics (gabapentin, lacosamide, levetiracetam, oxcarbazepine, pregabalin, topiramate, zonisamide). **Applicability.** A broader use can be made of other antiepileptics (gabapentin, levetiracetam, topiramate and oxcarbazepine) than of retigabine, particularly as monotherapy for partial epilepsy and for children older than 6 years.

Ease of use. Retigabine has no advantages in ease of use in comparison with the other antiepileptics (gabapentin, lacosamide, levetiracetam, oxcarbazepine, pregabalin, topiramate, zonisamide).

Volgnr: 2011079920 V1 Zaaknummer: 2011008440 **Final conclusion.** As an adjunctive treatment for partial epilepsy, the therapeutic value of retigabine is comparable with that of gabapentin, lacosamide, levetiracetam, oxcarbazepine, pregabalin and topiramate.

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