

Pharmacotherapeutic re-assessment report on rasagiline (Azilect®) for the treatment of idiopathic Parkinson's disease.

Summary

The Medicinal Products Reimbursement Committee (CFH) has carried out a re-assessment of the medicine rasagiline (Azilect®). Rasagiline is indicated for the treatment of idiopathic Parkinson's disease as monotherapy (without levodopa) as well as use as adjunct therapy (with levodopa) in patients with end-of-dose fluctuations.

De CFH assessed rasagiline earlier in April 2006 (CFH-rapport 06/10: rasagiline (Azilect®), April 2006). The conclusion of the earlier assessment was that there were no clinically relevant differences in properties between rasagiline and selegiline. This resulted in the statement that the two drugs are interchangeable and can be clustered with one another on List 1A.

The manufacturer did not agree with the opinion of the CFH and took the case to court. In February 2007 the District Court of Haarlem set up a committee of experts. On March 31, 2008, in an expert report, they concluded that the clinical efficacy of selegiline and rasagiline appear to be similar, both in monotherapy and as adjunct therapy (with levodopa).

In this re-assessment the CFH focused on new information. These are only data on rasagiline monotherapy in early treatment. The CFH believes that the new data confirm that there is insufficient evidence for an effect of rasagiline and selegiline on disease progression. The conclusion is therefore that no clinically relevant difference in properties has been demonstrated between rasagiline and selegiline. The committee is keeping to its viewpoint, that rasagiline is interchangeable with selegiline and that its clustering with selegiline can continue.