Pharmacotherapeutic report, summary

Rilpivirine (Edurant®) for the indication 'infection with HIV-1'

Approved on 26 March 2012 by the Medicinal Products Reimbursement Committee (CFH)

Medicine. Rilpivirine (hydrochloride) 25 mg, film-coated tablet.

Registered indication. "in combination with other antiretroviral medicinal products: treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with a viral load ≤ 100,000 HIV-1 RNA copies/ml."

Posology. 1 tablet once daily.

Working mechanism. Rilpivirine inhibits the activity of reverse-transcriptase, the HIV-enzyme that converts viral RNA into viral DNA. As a result the drug interrupts virus replication.

Summary of the therapeutic value

Intended effects. In adult, previously untreated patients with an HIV-infection and a virus concentration ≤ 100,000 copies/mL, the use of rilpivirine does not lead more frequently to a virologic response than the use of efavirenz, whereby both were combined with emtricitabine and tenofovir. The reliability of the underlying sub-group analysis is uncertain. The outcomes on the number of CD4-cells or HIV-related infections are unknown. In the event of virologic failure of the rilpivirine combination, cross-resistance to NRTIs occurs more frequently than with virologic failure of the efavirenz combination.

Unintended effects. The use of rilpivirine results less frequently in adverse effects, and these are less severe than when efavirenz is used.

Experience. Experience with rilpivirine is limited while considerable experience has been obtained with rilpivirine.

Applicability. The applicability of rilpivirine is more limited than efavirenz, because rilpivirine is not registered for children, nor for adults who have been treated previously with antiretroviral drugs or who have a virus concentration > 100,000 copies/ml.

Ease of use. Rilpivirine and efavirenz have the same ease of use.

Final conclusion. For the treatment of adult, therapy-naive patients infected with HIV-1 and with a virus concentration ≤ 100,000 copies/mL, the therapeutic value of the combination rilpivirine-emtricitabine-tenofovir is comparable with that of the combination efavirenz-emtricitabine-tenofovir.

*The original text of this **CFH report** of CVZ was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of CVZ's CFH-report.*
Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.