

## AWMSG Secretariat Assessment Report – Limited submission

### Rilpivirine (Edurant<sup>®</sup>▼) 25 mg film-coated tablets

**Company:** Janssen-Cilag Ltd

**Licensed indication under consideration:**

Rilpivirine (Edurant<sup>®</sup>▼) in combination with other antiretroviral medicinal products for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve patients from 12 years old to < 18 years old with a viral load ≤ 100,000 HIV-1 RNA copies/ml.

**Date of licence extension:** 20 November 2015

### Comparator(s)

- Nevirapine (generic and Viramune<sup>®</sup>)
- Efavirenz (Sustiva<sup>®</sup>)

### Limited submission details

- Minor licence extension
- Anticipated usage in NHS Wales is considered to be of minimal budgetary impact
- Estimated small difference in cost compared to comparators

### Clinical effectiveness

- Rilpivirine (Edurant<sup>®</sup>▼) was previously licensed for use in antiretroviral-naïve adults (recommended as an option for use by AWMSG in 2012); the licence has been extended to include adolescents aged 12 to < 18 years of age.
- The company submission includes a 48 week, phase II, open-label, single arm study (C213) evaluating the pharmacokinetics, safety, tolerability and antiviral efficacy of rilpivirine 25 mg once daily in combination with other antiretroviral agents (n = 36). The Committee for Medicinal Products for Human Use (CHMP) concluded that the overall efficacy in adolescents was acceptable.
- CHMP stated that the number of youngsters having virological failure, and with resistance development to both the non-nucleoside reverse transcriptase inhibitor (NNRTI) and the nucleoside reverse transcriptase inhibitor (NRTI) class within a year of therapy was of concern. The Summary of Product Characteristics (SPC) stipulates that only adolescents deemed likely to have good adherence to antiretroviral therapy should be treated with rilpivirine, as suboptimal adherence can lead to development of resistance and the loss of future treatment options.
- No new adverse drug reactions were identified in adolescents compared to those seen in adult patients. Treatment-related adverse effects (TEAEs) were reported in 13 (36.1%) patients. Depression was reported more often in adolescents (19.4%) compared to adults from the Phase III studies ECHO and THRIVE (4.1%). Rilpivirine combined with the background regimen of two NRTIs was considered generally safe and well-tolerated.

## Budget impact

- The company estimates that one patient in Wales would be eligible for rilpivirine within the indication under consideration, based on data from the Collaborative HIV Paediatric Study (CHIPS), which estimates that there are 12 children (aged up to 17 years) with HIV in Wales of which 6.39% are 12–17 years of age and are treatment-naive. The number of eligible patients is expected to be constant across the years.
- The budget impact is based on one patient receiving the maximum recommended daily dose for patients aged 12 years or over (25 mg once daily). The company have estimated the maximum total budget impact for the licence extension to be £2,403 per annum; however this does not take into account the displacement of comparator(s). AWTTTC calculated the budget impact to be £2041 if efavirenz (generic) was displaced and £2089 if nevirapine (generic) was displaced.

## Additional information

- AWTTTC is of the opinion that, if recommended, rilpivirine (Edurant<sup>®</sup>▼) is appropriate for specialist only prescribing within NHS Wales for the indication under consideration.
- The company anticipate that rilpivirine (Edurant<sup>®</sup>▼) may be supplied by a home healthcare provider.

## Evidence search

**Date of evidence search:** 6 April 2016

**Date of range of evidence search:** No date limits were applied to database searches.

## Further information

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTTC at [AWTTTC@Wales.nhs.uk](mailto:AWTTTC@Wales.nhs.uk) for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Rilpivirine (Edurant<sup>®</sup>▼) 25 mg film-coated tablets. Reference number: 2936. July 2016.