

# ETRAVIRINE (ETV)

## GENERAL INFORMATION

- Therapeutic class: Non-nucleoside reverse transcriptase inhibitor (NNRTI).
- WHO guidelines: Listed in the WHO guideline as potential third-line drug.<sup>6</sup> Approved by U.S. Food and Drug Administration (FDA) for treatment experienced adult patients who have evidence of resistance to an NNRTI and other antiretroviral agents.<sup>149</sup>
- Originator company and product brand name: Tibotec (a subsidiary of Johnson & Johnson), Intelence.
- First approval by U.S. Food and Drug Administration (FDA): January 2008.<sup>23</sup>
- WHO Model List of Essential Medicines (EML): Not included in the 17th edition.<sup>24</sup>
- World sales of originator product: There are no sales figures listed in the companies' annual report.
- Patents: The basic patent on etravirine was applied for by Janssen Pharmaceutica in 1999 and is due to expire in 2019.<sup>150</sup> In 2006, Tibotec applied for subsequent patents related to novel series of bisaryl substituted pyrimidine derivatives. Both Janssen Pharmaceutica and Tibotec are subsidiaries of Johnson & Johnson.<sup>151, 152</sup>

## PRICE INFORMATION

### Developing country prices in US\$ per patient per year, as quoted by companies.

The price in brackets corresponds to the price of one tablet.

|                            | Daily dose | Tibotec        |
|----------------------------|------------|----------------|
| Who can access this price? |            | See annex 2    |
| ETV 100mg tablet           | 4          | 913<br>(0.625) |

## SPOTLIGHT ON ACCESS ISSUES

In 2010, WHO released new recommendations which for the first time call for the need of third-line therapy. Many studies are ongoing; drugs likely to have anti-HIV activity in third-line regimens are etravirine (ETV), boosted darunavir (DRV), and raltegravir (RAL).<sup>7</sup>

In August 2009, Tibotec (a subsidiary of Johnson & Johnson) signed a royalty-free, non-exclusive licence agreement with Aspen of South Africa covering all of sub-Saharan Africa for all ETV formulations. Under this agreement, Aspen will handle regulatory and distribution activities. At the time of writing, Aspen/Tibotec ETV 100mg tablet is registered in at least six countries in

sub-Saharan Africa with applications in process in sixteen others.

The price of ETV, at \$913 ppy, is prohibitive for developing countries. There is no generic version of this drug yet available.

### Patents

Patents have been applied for widely in the developing world, including in Africa. Janssen Pharmaceutica obtained the molecule patent in India<sup>153</sup> and China.<sup>38</sup>

This patent will block the development of generic formulations of ETV, unless licences – voluntary or compulsory – are issued to generic companies for the manufacture of affordable versions of the drug.

In India, Tibotec has filed additional patent applications<sup>154</sup> on new forms which, if granted, will extend its monopoly in India from 2021 to 2027.

### Paediatrics

ETV is not approved for use in children today. A waiver of paediatric studies from birth to two months was granted by EMA on grounds that the medicine does not represent significant therapeutic benefit over existing treatments.<sup>155</sup>

As few treatment options exist for children with HIV, it is critical that paediatric studies of ETV be completed and adapted formulations be made available.